No. WD60501

IN THE MISSOURI COURT OF APPEALS
WESTERN DISTRICT

STATE BOARD OF REGISTRATION FOR THE HEALING ARTS, Appellant

vs.

EDWARD W. MCDONAGH, Respondent

Appeal from the Circuit Court of Cole County, Missouri
Nineteenth Judicial Circuit
Honorable Byron Kinder, Circuit Judge

CORRECTED BRIEF OF APPELLANT STATE BOARD OF REGISTRATION FOR THE HEALING ARTS

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JURISDICTIONAL STATEMENT

This appeal is from a decision of the State Administrative Hearing Commission based on Findings of Fact and Conclusions of Law of the Missouri Administrative Hearing Commission entered on January 26, 2000. The Circuit Court of Cole County, Missouri, affirmed the Administrative Hearing Commission on September 21, 2001. An appeal of the Circuit Court=s decision is provided for in Section 536.140.6, RSMo 1994, as well as Article V, Section 18, Missouri Constitution. This appeal involves no issue within the exclusive jurisdiction of Missouri Supreme Court and this Court has jurisdiction. Article V, Section 3, Missouri Constitution.

STANDARD OF REVIEW

Judicial review of the orders of the Administrative Hearing Commission is authorized under the provisions of Sections 621.145, RSMo 1994, as well as Sections 536.100 through 536.150, RSMo 1994. The order and decision of the Administrative Hearing Commission in this case, as represented by its ***Findings of Fact and Conclusions of Law*** of the Administrative Hearing Commission, entered on January 26, 2000, may be reviewed and challenged if the agency action:

(A) is in excess of statutory authority and/or jurisdiction of the Commission;

(B) is unsupported by competent and substantial evidence upon the whole record;

(C) is unauthorized by law;

(D) is arbitrary, capricious and unreasonable;

(E) involves abuse of discretion;

(F) erroneously announces and applies Missouri law;

and therefore is reviewable by this Court under the provisions of Sections 621.145, RSMo 1994, and Section 536.140, RSMo 1994.

In an administrative appeal, the courts must review the decision of the administrative agency rather than the Circuit Court. *Psyhcare Mgt. v. Dept. of Social Services*, 980 S.W.2d 311, 312 (Mo. banc 1998). The court=s review of an administrative decision is clearly defined, and limited in scope. The Administrative Hearing Commission (AAHC@) decision must be upheld if it is supported by substantial evidence upon the whole record. RSMo 536.140.2(3). The record must be viewed in the light most favorable to the AHC decision. *State Bd. of Registration for the Healing Arts v. Finch*, 514 S.W.2d 608, 618 (Mo. App. 1974).

The Missouri Administrative Procedure Act, Section 536.130.2(3), RSMo 1994, provides that the court must review the underlying administrative decision to determine if findings of fact are supported by competent and substantial evidence upon the whole record. The evidence in support of an administrative agency finding must be sufficient to support the conclusion of a reasonable person after considering all of the evidence in the record as a whole, not just the evidence that is consistent with the agency=s finding. *Universal Camera Corp. v. NLRB*, 340 U.S. 471, 488 (1951). In the *Universal Camera* case, the United States Supreme Court held that A[t]he substantiality of evidence must take into account whatever in the record fairly detracts from its weight.@ *Id.*

STATEMENT OF FACTS

I. BACKGROUND

EDTA (ethylene diamine tetra-acetic acid) is a drug approved by the Federal Food and Drug Administration for the removal of heavy metals in the body and only for that purpose. **(FOF #9, page 3; ROA at 180; Pet. Ex. 13, page 20, line 7-8))**.[1] Since the 1950's, a handful of physicians have purported to treat atherosclerosis (hardening of the arteries) and other vascular diseases with EDTA chelation therapy. EDTA chelation therapy involves the intravenous administration of a diluted solution containing EDTA, and frequently other substances, over a period of several hours time. EDTA chelation therapy is not generally accepted by the medical (allopathic and osteopathic) community of the United States as effective for the treatment of any human malady other than the removal of heavy metals from the body. **Petitioner=s Ex. 24-28; Tr. 914-918)**.[2] EDTA chelation therapy is rejected and is

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[1] FOF #__, page ___ refers to a specific Finding of Fact by Administrative Hearing Commission (AHC); ROA at __ refers to a specific page of the Record on Appeal and does not include those volumes pertaining to the AHC Transcript

[2] Petitioner=s Ex. __ or Pet. Ex. __ refers to a specific exhibit admitted into the record at the Administrative Hearing Commission; Tr. __ refers to a specific page of the

considered a disproven therapy by the overwhelming majority of physicians in this country for the treatment of atherosclerosis and other vascular diseases.

Petitioner, the Missouri State Board of Registration for the Healing Arts, is an agency of the State of Missouri created and established pursuant to Section 334.120, RSMo, for the purpose of executing and enforcing the provisions of Chapter 334, RSMo, Physicians and Surgeons, the Missouri Healing Arts Practice Act. Respondent, Edward W. McDonagh, D.O., is licensed by Petitioner as an Osteopathic physician and surgeon whose license No. DO27972 is, and at all times hereinafter mentioned was, current and active. Respondent primarily practices in the area of family medicine. **(FOF #2, page 2; ROA at 179)**. Respondent has practiced medicine in Missouri since 1962. Respondent claims to have a practice centered on preventive medicine. Respondent has used EDTA chelation therapy in the treatment of human maladies other than heavy metals poisoning since 1962. In particular, respondent has offered EDTA chelation therapy to treat atherosclerosis and other vascular diseases. Respondent advertises heavily, including having a presence on the Internet. Respondent offers a number of treatment modalities which he describes as alternative. EDTA chelation therapy, however, is one of Respondent=s primary treatment modalities. Respondent and a few other physicians claim that infusions of EDTA into the bloodstream can remove plaque from the arteries and thereby halt the progress of atherosclerosis and other vascular diseases. **(Tr. 1255)**.

1997 AHC Transcript which was filed as its own separate ROA.

Respondent claims to be able to treat any number of diseases with chelation, including atherosclerosis, diabetes, gangrene and numerous other chronic diseases.

The Missouri State Board of Healing Arts has reviewed the subject of the efficacy of EDTA chelation therapy a number of times over the years. In 1989, the Board considered passing a rule holding that EDTA chelation therapy is of no medical or osteopathic value under the provisions of Section 334.100.2(f), RSMo 1986. After reviewing the literature on EDTA chelation therapy, the Board announced that it would not pursue a rule on EDTA chelation therapy, in light of the lack of scientific evidence in the form of a controlled clinical trial establishing that it is not effective in the treatment of vascular disease. The Board stated in 1989 that it would consider citizen complaints about EDTA chelation therapy on a case-by-case basis and would give attention to whether the practitioner complied with recognized protocols on the use of EDTA chelation therapy. **(Respondent=s Ex. B-1)**.[3]

The Guldager study published in 1992 and the Van Rij study published in 1994 were large, well-designed studies, both of which concluded that EDTA chelation therapy was not

[3] Respondent=s Ex. __ or Resp. Ex. __ refers to a specific exhibit admitted into the record at the Administrative Hearing Commission. By agreement the parties will supplement ROA with copies of all exhibits referred to in the appeal briefs.

effective in the treatment of atherosclerosis. The Guldager and Van Rij studies have both been generally accepted by medical science as scientifically valid. **(FOF #25, #27, pages 9-10; ROA at 186-87)**. As of the publication of the Van Rij study in 1994, EDTA chelation therapy in the treatment of atherosclerosis had been proven to be ineffective according to the generally accepted requirements of medical science. The Van Rij study in 1994 replicated the results of the Guldager study in 1992 and authoritatively answered the question of the efficacy of EDTA chelation therapy in the treatment of atherosclerosis. **(Tr. 126)**.

Respondent is a member of The American Osteopathic Association and has relied on their certification to establish his own competency. The American Osteopathic Association, an independent association of physicians organized to advance the philosophy and practice of osteopathic medicine, Adoes not endorse chelation therapy as useful for [any application or treatment] other than its currently approved and medically accepted uses.@ **(Petitioner=s Exhibit 24)**.

The American Medical Association issued the following statement about EDTA chelation therapy in 1994:

> There is no scientific documentation that the use of chelation is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer. If chelation is to be considered a useful medical treatment for anything other than heavy metal poisoning, hypercalcemia, or digitalis toxicity[4], it is the

[4]At this point in time, the FDA had approved EDTA for the treatment of digitalis

> responsibility of its proponents to conduct properly controlled scientific studies to adhere to FDA guidelines for drug investigation and to disseminate study results in the usually accepted channels. The AMA believes that chelation for atherosclerosis is an experimental process without proof in efficacy.

(Pet. Ex. 26).

There is also evidence in the record that the general medical community has not recognized EDTA chelation therapy for treating cardiovascular disease, particularly arteriosclerosis, as a generally accepted medical practice. **(Pet. Ex. 12; Testimony of David G. Meyers, M.D., Tr. 188, line 24 to Tr. 189, line 6; Pet. Ex. 19 (Deposition of Alfred Soffer, M.D.).** The American Heart Association's Task Force on New and Unestablished Therapies reviewed the available literature on the use of chelation and found "no scientific evidence to demonstrate any benefit from this form of therapy." **(Pet. Ex. 25)**. The American College of Cardiologists has also issued a similar statement on EDTA chelation=s ineffectiveness. **(Pet. Ex. 26)**.

Respondent=s primary expert witness, Dr. James P. Frackleton, M.D., squarely admitted that EDTA chelation therapy is not generally accepted in the medical profession in this country as efficacious for the treatment of atherosclerosis. **(Testimony of Dr. James P. Frackleton, Tr. 713, line 9, to Tr. 714, line 5)**. Dr. Frackleton, admitted in his testimony that EDTA

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toxicity in addition to the removal of heavy metals from the body.

chelation therapy is not generally accepted in either the allopathic community or the osteopathic community. **(*Id.*, at 714, lines 15-19)**. Dr. Frackleton blamed the failure of organized medicine to embrace chelation therapy on ignorance.

Q. My question is this. Can we agree that the use of EDTA chelation to treat atherosclerosis is not at this point in time generally accepted in the medical profession in this country as efficacious for the treatment of atherosclerosis?

A. I would think that's probably true through ignorance of their part.

Q. I understand you don't agree with it and we'll talk about that.

A. I agree with your statement but it's through their ignorance, yes.

Q. I understand you don't think that's right, but it is at this point in time not generally accepted in the medical profession; that's the case, is it not?

A. I would think so, certainly.

Q. And that's been true in the allopathic end of the business, which you're an MD and you belong to, and the osteopathic end of the business for DOs like Dr. McDonagh; is that a fair statement?

A. True.

(Tr. 713, line 23, to Tr. 714, line 19).

II. BOARD COMPLAINT AND ASSERTIONS

The Board's Complaint against Respondent arose out of two separate patient complaints received by the Board of Healing Arts in the year 1992. Each of the patients

complained about Respondent=s use of EDTA chelation therapy. The Board filed the original Complaint against Respondent in the year 1994[5], only after the publication of the Guldager and Van Rij studies, both of which were generally accepted in the medical profession as establishing that EDTA chelation therapy is ineffective in the treatment of vascular diseases.

On December 6, 1996, Petitioner re-filed its Complaint in the Administrative Hearing Commission, State of Missouri, seeking a finding of cause to discipline the license of Respondent based on thirteen (13) counts of alleged violations of the Missouri Healing Arts Practice Act, Section 334.100, et seq, RSMo. **(ROA 2-22)**. In Count I of Petitioner=s Complaint Petitioner charged that Respondent violated the applicable standard of care by utilizing EDTA chelation therapy to treat atherosclerosis and other vascular diseases. Petitioner presented extensive expert testimony demonstrating that EDTA chelation therapy does not meet the standard of care for treating atherosclerosis and other vascular diseases. **(*Id*., at 3)**.

Petitioner filed a Motion in Limine **(Tr. 5-7, 346; ROA at 39)** and at trial moved to strike respondent=s expert testimony presented in support of chelation therapy (Dr. McDonagh, Dr. Charles Rudolph, Dr. James P. Frackleton, and Dr. L. Terry Chappell) based on the *Frye* rule. *Frye v. United States*, 293 F. 1013 (1923). The

[5]The Board=s original Complaint was dismissed without prejudice and the current Complaint was refiled shortly after on December 6, 1996.

parties agreed that Respondent=s expert testimonial evidence would be taken on the record subject to Petitioner=s ongoing general objection to the admission of all expert testimony in support of the efficacy of chelation therapy. **(Tr. 5-7; 346; R. at 39).**

Petitioner presented a number of expert witnesses who testified that EDTA chelation therapy does not meet the standard of care for the treatment of atherosclerosis or other vascular diseases. **(Meyers= Testimony, Tr. 177-186; Pet. Ex. 12 (Kyner Deposition); Pet. Ex. 13 (Soffer Deposition; Pet. Ex. 15 (Green Deposition)**. Respondent=s own expert medical witness, Dr. James P. Frackleton, admitted that EDTA chelation therapy is not generally accepted in the medical profession as efficacious in the treatment of vascular diseases. **(Testimony of Dr. James P. Frackleton, Tr. 713, line 9, to Tr. 714, line 5)**. The Administrative Hearing Commission made no finding of fact to the effect that EDTA chelation therapy is generally accepted in the scientific community to which it belongs. **(ROA at 178-247)**.

Respondent=s experts, including respondent himself, testified in terms of his patient care meeting Athe standard of care,@ without ever defining that term in accordance with the statutory definition of negligence, Athe failure . . . to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member(s) of the . . . licensee=s profession.@ Section 334.100.2(5), RSMo 1994. The Board=s primary expert, Dr. David G. Meyers, specifically testified that the term Astandard of care,@ as he used it in his testimony,

equated to the statutory language of Athe failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of the licensee=s profession.@ **(Tr. 174-76).**

Count I of the Complaint, paragraph 7, alleges that ARespondent has misrepresented that atherosclerosis and various other diseases, ailments, and infirmities can be cured by EDTA chelation therapy.@ **(ROA at 3).** This allegation falls under Section 334.100.2(4)(e), which provides a basis for discipline when a licensee has Amisrepresented that any disease, ailment or infirmity can be cured by a method, procedure, treatment, medicine, or device.@ Respondent has claimed for years that EDTA chelation therapy can cure atherosclerosis. Respondent claims in his pamphlet, A*Reversing Degeneration and Aging Through Chelation*,@ that Awe have a program to remove arterial scale and a program to keep blood vessels open in the future.@ **(Pet. Ex. 29)**. Petitioner presented evidence at trial that this claim is false and that Respondent has no valid scientific evidence to substantiate his claims. In his 1987 book *Chelation Can Cure*, Respondent makes a number of claims that he can cure atherosclerosis with EDTA chelation therapy. An example:

> Chelation neutralizes and removes the earliest and most basic cause of degenerative disease in the human body. Safe, thorough removal of the occluding materials that stick to the inside of the arteries is accomplished all over the body. Organs that have lost function because of circulatory embarrassment have their function restored, without the use of drugs.

(Respondent=s Exhibit C-1, page 139) (emphasis supplied) . Respondent claims that EDTA

chelation therapy Ais more effective than any other treatment.@ He says that A[s]afe, thorough removal of the occluding materials that stick to the inside of the arteries is accomplished all over the body.@ **(Id.)**.

In Count V of the Complaint, Petitioner charged that Respondent attempted to treat an elderly male patient with diabetes and gangrene with EDTA chelation therapy. **(ROA at 8-10)**. Petitioner=s expert medical witness testified that EDTA chelation therapy is not generally accepted in the medical profession as within the standard of care in the treatment of diabetes or gangrene. The patient ultimately had to be rushed to a local hospital where surgeons were forced to amputate his gangrenous leg.

Petitioner charged in all Counts of the Complaint but three that Respondent routinely violated the provisions of Section 334.100.2(4) (a), (c), and (5) by willfully and continually performing inappropriate or unnecessary treatment, tests or medical services. Petitioner=s evidence demonstrated that Respondent routinely and habitually orders numerous unnecessary tests on his patients and makes a profit off the testing. Dr. David G. Meyers testified on behalf of the petitioner that numerous tests given to patients were not Anecessary,@ as required by Section 334.100.2(4)(c), RSMo. Respondent presented no substantial evidence that any such testing was Anecessary.@

III. ADMINISTRATIVE PROCEEDINGS

After a trial in November, 1997, the Administrative Hearing Commission on January 26, 2000, issued its *Findings of Fact and Conclusions of Law,* finding no basis for discipline of Respondent=s medical license. **(ROA at 179-247).** The Missouri State Board of

Registration for the Healing Arts, hereby petitions this Court for judicial review of the order and decision of the Administrative Hearing Commission, in the form of the *Findings of Fact and Conclusions of Law* issued by the Commission in the captioned case on January 26, 2000, such order and decision finding no basis for the discipline of Respondent=s license under the applicable provisions of the Missouri Healing Arts Practice Act, Section 334.100.2, RSMo, as applicable and in effect at various times to the conduct of Respondent. The Circuit Court of Cole County, Missouri, upheld the findings of the AHC on September 21, 2001. This appeal followed. **(ROA at 682)**.

Judicial review is authorized under Section 621.145, RSMo 1994, as well as Sections 536.100 through 536.150, RSMo 1994. Petitioner is an aggrieved party or agency, within the meaning of Section 621.145 and Section 536.100, as the Board was aggrieved by a final decision in a contested case before the Administrative Hearing Commission.

POINTS RELIED ON

I. ***THE ADMINISTRATIVE HEARING COMMISSION ERRED AND ABUSED ITS DISCRETION BY ADMITTING INTO EVIDENCE AND RELYING ON AS SUBSTANTIAL EVIDENCE RESPONDENT=S EXPERT MEDICAL TESTIMONY IN SUPPORT OF HIS USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES, BECAUSE: (1) RESPONDENT=S EXPERT TESTIMONY DID NOT REST ON SCIENCE MEETING THE GENERAL ACCEPTANCE TEST UNDER FRYE V. UNITED STATES, IN THAT THE COMMISSION MADE NO FINDING, AS REQUIRED UNDER FRYE, THAT EDTA CHELATION THERAPY RESTS ON SCIENTIFIC METHODOLOGY GENERALLY ACCEPTED IN THE SCIENTIFIC FIELD IN WHICH IT BELONGS; AND (B) RESPONDENT=S EXPERT WITNESSES TESTIFIED IN TERMS OF CHELATION THERAPY MEETING THE ASTANDARD OF CARE@ AND FAILED TO FRAME THEIR TESTIMONY IN TERMS OF THE STATUTORY LANGUAGE OF SECTION 334.100.2(5), RSMo,TO-WIT:ATHAT DEGREE OF SKILL AND LEARNING ORDINARILY USED UNDER THE SAME OR SIMILAR CIRCUMSTANCES BY THE MEMBER(S) OF THE . . . LICENSEE=S PROFESSION,@ AND THEREFORE THERE IS NO COMPETENT AND SUBSTANTIAL EVIDENCE IN THE RECORD TO SUPPORT THE COMMISSION=S FINDINGS THAT CHELATION THERAPY IS EFFECTIVE.***

Authorities:

M.C. v. Yeargin, 11 S.W.3d 604 (Mo. App. E.D. 1999)

Alsbach v. Bader, 700 S.W.2d 823, 828-29 (Mo. banc 1985)

State v. Biddle, 599 S.W.2d 182, 185 (Mo. 1980)

Ladish v. Gordon, 879 S.W.2d 623 (Mo. App. W.D. 1994)

Bever v. State Board of Registration for the Healing Arts,

2001WL 68307 *5, *7(Mo.App. W.D. 2001)

II. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN FINDING THAT EDTA CHELATION THERAPY MEETS THE STANDARD OF CARE FOR THE TREATMENT OF ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES, BECAUSE, EDTA CHELATION THERAPY IS NOT GENERALLY ACCEPTED WITHIN THE MEDICAL PROFESSION AS EFFECTIVE IN THE TREATMENT OF ATHEROSCLEROSIS OR OTHER VASCULAR DISEASES, AND, IN ADDITION, WHILE THERE MAY OR MAY NOT BE A AGOOD FAITH DISPUTE AMONG COMPETENT PHYSICIANS@ AS TO THE EFFECTIVENESS OF EDTA CHELATION THERAPY FOR THIS USE, IN THAT THE USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS OR OTHER VASCULAR DISEASES IS NONETHELESS AAGAINST THE COURSE RECOGNIZED AS CORRECT BY THE MEDICAL PROFESSION GENERALLY,@ AND SUCH TREATMENT THEREFORE DOES NOT MEET THE STANDARD OF CARE UNDER MISSOURI LAW THEREFORE ON THIS ISSUE THE AHC ERRONEOUSLY ANNOUNCED AND APPLIED MISSOURI LAW.

Authorities:

Haase v. Garfinkel, 418 S.W.2d 108 (Mo. 1967)

Green v. Ralston Purina Co., 376 S.W.2d 119 (Mo. 1964)

Hurlock v. Park Lane Med. Center, Inc., 709 S.W.2d 872(Mo.App. W.D. 1985)

III. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN THAT THE COMMISSION FAILED TO MAKE REQUIRED FINDINGS OF FACT AND CONCLUSIONS OF LAW ON PETITIONER=S CLAIM IN ITS COMPLAINT TO THE EFFECT THAT RESPONDENT MISREPRESENTED THAT ATHEROSCLEROSIS, DIABETES, GANGRENE AND NUMEROUS OTHER DISEASES CAN BE CURED BY EDTA CHELATION THERAPY, BECAUSE THE LAW REQUIRES THE COMMISSION TO MAKE SPECIFIC FINDINGS OF FACT ON CONTESTED FACT ISSUES, IN THAT THE COMMISSION SHOULD HAVE FOUND THE FACTS IN FAVOR OF THE BOARD ON THE MISREPRESENTATION CLAIM, BASED ON THE SUBSTANTIAL EVIDENCE OF RECORD DEMONSTRATING RESPONDENT=S MANY STATEMENTS THAT CHELATION THERAPY CAN CURE NUMEROUS DISEASES.

Authorities:

Missouri Bd. of Pharmacy v. Tadrus, 926 S.W.2d 132 (Mo.App. W.D. 1996).

Mineweld, Inc. v. Bd. of Boiler and Pressure Vessel Rules,

868 S.W.2d 232 (Mo.App. W.D. 1994)

Missouri Dental Bd. v. Bailey, 731 S.W.2d 272 (Mo.App. W.D. 1987)

Emily v. Bayne, 371 S.W.2d 663 (Mo. App. 1963)

IV. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN

ARBITRARILY REJECTING PETITIONER=S SUBSTANTIAL EVIDENCE THAT RESPONDENT FAILED TO KEEP AND MAINTAIN PATIENT RECORDS IN ACCORDANCE WITH THE APPLICABLE STANDARD OF CARE, BECAUSE THE COMMISSIONER ARBITRARILY DECIDED THAT A PHYSICIAN CANNOT BE DISCIPLINED BASED ON INADEQUATE RECORD-KEEPING IN THE ABSENCE OF A STATUTE OR BOARD RULE MANDATING SPECIFIC RECORD-KEEPING DUTIES ON THE PART OF MISSOURI PHYSICIANS IN THAT THE STANDARD OF CARE ESTABLISHES RESPONDENT=S PATIENT RECORD-KEEPING RESPONSIBILITIES.

Authorities:

Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951)

Wright v. Sports Associated, Inc., 887 S.W.2d 596 (Mo. banc. 1994)

Barnes Hosp. v. Missouri Comm=n on Human Rights,

661 S.W.2d 534, 537 (Mo. en banc 1983)

State ex rel. Kahler v. State Tax Comm=n, 393 S.W.2d 460 (Mo. 1965)

V. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN FAILING TO MAKE THE REQUIRED FINDINGS OF FACT ON AND ARBITRARILY REJECTING SUBSTANTIAL EVIDENCE SUPPORTING PETITIONER=S REQUESTED FINDINGS OF FACT ON PETITIONER=S CLAIM THAT RESPONDENT REPEATEDLY CONDUCTED AND PERFORMED INAPPROPRIATE AND UNNECESSARY TESTING ON PATIENTS IN VIOLATION OF SECTION 334.100.2(4)(c), AND (5), RSMO, TO-WIT: HEMOGLOBIN A1C TESTING, BECAUSE THE COMMISSION DID NOT

HAVE LEGAL AUTHORITY TO ARBITRARILY REJECT UNCONTROVERTED EXPERT TESTIMONY AND ACCEPT MERE CONCLUSORY, SKETCHY AND SLIGHT EXPERT TESTIMONY NOT CONSTITUTING SUBSTANTIAL EVIDENCE, IN THAT PETITIONER PRESENTED SUBSTANTIAL EVIDENCE DEMONSTRATING REPEATED INAPPROPRIATE AND UNNECESSARY TESTING ON PATIENTS BY RESPONDENT, WHICH EVIDENCE WAS UNCONTROVERTED IN THAT NO EXPERT WITNESS TESTIFIED THAT THE REPEATED HEMOGLOBIN A1C TESTING WAS ANECESSARY@ AND THERE WAS NO SUBSTANTIAL EXPERT TESTIMONY PRESENTED BY RESPONDENT THAT ANY OF THE QUESTIONED TESTING WAS ANECESSARY,@ THE AOBJECTIVE LEGAL STANDARD@ ESTABLISHED BY SECTION 334.100.2(4)(c), RSMO.

Authorities:

Missouri Bd. of Pharmacy v. Tadrus, 926 S.W.2d 132 (Mo. App. W. D. 1996)

Wright v. Sports Associated, Inc., 887 S.W.2d 596 (Mo. en banc. 1994)

Barnes Hosp. v. Missouri Comm:n on Human Rights,

661 S.W.2d 534 (Mo. banc 1983)

State ex rel. Kahler v. State Tax Comm:n, 393 S.W.2d 460, 465 (Mo. 1965)

Section 334.100.2(4)(c), (5), RSMo 1994

ARGUMENT

I. ***THE ADMINISTRATIVE HEARING COMMISSION ERRED AND ABUSED ITS DISCRETION BY ADMITTING INTO EVIDENCE AND RELYING ON AS SUBSTANTIAL EVIDENCE RESPONDENT=S EXPERT MEDICAL TESTIMONY IN SUPPORT OF HIS USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES, BECAUSE: (A) RESPONDENT=S EXPERT TESTIMONY DID NOT REST ON SCIENCE MEETING THE GENERAL ACCEPTANCE TEST UNDER FRYE V. UNITED STATES, IN THAT THE COMMISSION MADE NO FINDING, AS REQUIRED UNDER FRYE, THAT EDTA CHELATION THERAPY RESTS ON SCIENTIFIC METHODOLOGY GENERALLY ACCEPTED IN THE SCIENTIFIC FIELD IN WHICH IT BELONGS; AND (B) RESPONDENT=S EXPERT WITNESSES TESTIFIED IN TERMS OF CHELATION THERAPY MEETING THE ASTANDARD OF CARE@ AND FAILED TO FRAME THEIR TESTIMONY IN TERMS OF THE STATUTORY LANGUAGE OF SECTION 334.100.2(5), RSMo,TO-WIT:ATHAT DEGREE OF SKILL AND LEARNING ORDINARILY USED UNDER THE SAME OR SIMILAR CIRCUMSTANCES BY THE MEMBER(S) OF THE . . . LICENSEE=S PROFESSION,@ AND THEREFORE THERE IS NO COMPETENT AND SUBSTANTIAL EVIDENCE IN THE RECORD TO SUPPORT THE COMMISSION=S FINDINGS THAT CHELATION THERAPY IS EFFECTIVE.***

1. OVERVIEW.

Petitioner filed a Motion in Limine **(Tr. 5-7, 346; ROA at 39)** and at trial moved to strike respondent=s expert testimony presented in

support of EDTA chelation therapy (Dr. McDonagh, Dr. Charles Rudolph, Dr. James P. Frackleton, and Dr. L. Terry Chappell) based on the *Frye* rule. *Frye v. United States*, 293 F. 1013 (1923). Under the provisions of Section 536.070(7), RSMo 1994, even evidence to which an objection is sustained is normally made a part of the record in the Administrative Hearing Commission. The Commissioner ultimately denied and overruled Petitioner=s objections to Respondent=s expert medical testimony, holding that the record supported the admission of such testimony under both the *Frye* standard and, if applicable, the *Daubert* standard.

Under *Frye*, Respondent bore the burden of establishing on the record that the

scientific principles underlying the research on EDTA chelation therapy are generally accepted in the relevant scientific community in which it belongs. *M.C. v. Yeargin*, 11 S.W.3d 604, 619 (Mo. App. E.D. 1999). Respondent failed to bear this burden. Indeed, the record shows that EDTA chelation therapy has been widely discussed and overwhelmingly rejected by the medical profession. The data supporting EDTA chelation therapy does not rest on sound scientific methodology and therefore is not generally accepted as supporting the use of chelation therapy to treat

atherosclerosis and other vascular diseases.

The Commissioner failed to make the required finding that the principles underlying the research on EDTA chelation therapy, and the results thereof, are generally accepted in the scientific field to which it belongs. The failure to make such a finding is an abuse of discretion. *M.C. v. Yeargin*, at 619 (Fact finder abused its discretion in admitting expert testimony that was not based on scientific principles generally accepted in the relevant scientific community). Absent the expert medical testimony offered by Respondent and admitted into evidence by the Commissioner, Petitioner=s expert medical testimony that the use of EDTA chelation therapy to treat atherosclerosis and other vascular diseases is not within the standard of care was uncontroverted and required a finding in favor of Petitioner on the counts of Petitioner=s Complaint directed at Respondent=s use of EDTA chelation therapy.

B. ARGUMENT.

1. <u>The Applicable Standard of Review.</u>

The applicable standard of review is whether the trial court abused its sound discretion. *State v. Davis*, 814 S.W.2d 593 (Mo. banc 1991).

2. <u>Commissioner Reine Fails to Find that the Scientific Principles Underlying the Testimony of Respondent=s Expert Witnesses is Generally Accepted in the Relevant Scientific Community to Which it Belongs.</u>

(A) <u>*Frye* findings</u>

The Commissioner (Willard C. Reine) offers numerous rationalizations and justifications for admitting Respondent=s expert testimony, although he nowhere specifically makes a factual finding that EDTA chelation therapy is generally accepted in the particular field to which it belongs, the *Frye* standard requirement. In a similar case, the Eastern District Court of Appeals recently found an abuse of discretion on the part of the trial judge who admitted expert medical testimony without making a specific finding of general acceptance:

> We find that the trial court abused its discretion in admitting Dr. Bremner=s testimony because the court did not find that he based it on scientific principles generally accepted in the relevant scientific community or within the boundaries of Section 490.065 RSMo (1986). The trial court found there was a >sufficient and adequate basis= for Dr. Bremner to testify about a decrease in hippocampal volume. The Missouri Supreme Court continues to accept the *Frye* test to the admissibility of expert testimony The trial court failed to determine admissibility under the *Frye* test, additionally, there is no evidence that

> Dr. Bremner=s methodology of arriving at his theory of diminished hippocampal volume is generally accepted.

M.C. v. Yeargin, at 619.

As in *M.C. v. Yeargin*, Commissioner Reine did not make a specific finding that Respondent=s expert testimony, or any of it, was based on scientific principles generally accepted in the relevant scientific community. In denying and overruling Petitioner=s Motion in Limine and objection, Commissioner Reine had the following largely irrelevant comments:

> The Board argues that the *Frye* test and the last prong of the *Daubert* test would render testimony about this treatment inadmissible. We disagree. Approximately 1,000 doctors treat patients with chelation therapy for disorders other than heavy metal poisoning. They are organized into the American College for Advancement in Medicine, which performs studies, publishes articles, and has established a protocol for treatment. While the majority of doctors do not use chelation therapy in this way, it is an innovative use of a treatment by a minority of doctors. The off-label use of drugs is generally accepted by the medical profession. These facts indicate an >honest difference of opinion= under Missouri case law.[6]

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[6]To support this proposition, Commissioner Reine cites the negligence case of *Ladish v. Gordon*, 879 S.W.2d 623 (Mo. App. W.D. 1994). *Ladish v. Gordon* is a case involving the standard of care applicable where there is claimed to be an alternative standard

(COL, page 37-38).[7]

As can be seen, Commissioner Reine failed to make a specific finding that the scientific principles relied on by Respondent=s experts are generally accepted in the field to which they belong. Under the precedent of *M.C. v. Yeargin*, this constitutes an abuse of discretion and mandates a reversal. General acceptance may not be found A>[i]f there is a significant dispute between qualified experts as to the validity of scientific evidence.=@ *State v. David Wayne Kunze*, 988 P.2d 977 (Wash.App. 1999). In reality, Commissioner Reine established that the standards for admission under *Frye* were not met, given his findings of a difference of opinion in the profession.

(B) A**Standard of Care@ testimony**

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of care. The case does not purport to relate to the *Frye* standard and does not support the Commissioner=s point.

[7] COL __ refers to a specific page in the Conclusions of Law issued by the AHC in this case.

Section 334.100.2(5), RSMo, defines Arepeated negligence@ as Athe failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee=s profession.@ Commissioner Reine failed to make a finding of fact or conclusion of law that respondent was not guilty of Athe failure . . . to use that degree of skill and learning ordinarily used under the same or similar circumstances@ by the members of respondent=s profession. Commissioner Reine spoke in terms of broad generalities rather than in the language of the governing statute. Indeed, all of respondent=s experts, including respondent himself, spoke in terms of his patient care meeting Athe standard of care,@ without ever defining that term in accordance with the statutory definition of negligence.[8] Therefore, under the authority of *Bever v. State Board of Registration for the Healing Arts*, 2001WL 68307 *5, *7 (Mo.App. W.D. 2001) (Opinion

[8] Entire record. AQ Do you believe that your treatment and care of Mr. Jones back in 1979 through >81 and again in >91 met the standard of care? A Yes.@ **(Tr. 1011)**. Or *see* **Tr. 1032**: AQ Are you satisfied that you met the standard of care in providing the treatment that you did to Beverly Collins? A Yes.@

No. WD57880),[9] respondent=s defensive testimony in support of EDTA chelation therapy failed to rise to the level of substantial evidence.[10] The *Bever* decision extended to licensing discipline cases the rule established in *Ladish v. Gordon,* 879 S.W.2d 623 (Mo. App. W.D. 1994), that shorthand phrases like Astandard of care@ are not substantial evidence of medical negligence. 879 S.W.2d 623, 634-35 (Mo.App. W.D. 1993). In addition, in the absence of specific findings that track the terms of the statute, the Commission=s findings and conclusions are inadequate as a matter of law.

The Commissioner=s error and clear abuse of discretion in admitting and relying on Respondent=s expert medical testimony requires reversal and a remand to the Commission for

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[9] For the convenience of the Court, the *Bever* opinion is set out at Appendix A-71. The Board in the *Bever* case dismissed its appeal to the Supreme Court with the consent of Dr. Bever, in light of the fact that the Legislature had amended the Open Meetings Law to provide that Board disciplinary hearings may be held in closed session, thus mooting the issue present on that transfer. A disciplinary hearing was held by the Board on January 11, 2002. The Board imposed discipline of the revocation of Dr. Bever=s license with no reapplication for a period of two years. *See* Board=s Order at A-93.

[10]The Board=s primary expert, Dr. David G. Meyers, specifically testified that the term Astandard of care,@ as he used it in his testimony, equated to the statutory language of Athe failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of the licensee=s profession.@ Tr. 174-76.

a reconsideration of those counts of Petitioner=s Complaint related to Respondent=s use of EDTA chelation therapy.

3. <u>Off-label Use of drugs.</u>

In an effort to justify the admission of respondent=s expert testimony, Commissioner Reine broadly recites that off-label use of drugs is generally accepted in the medical profession. **(FOF #12, page 4; ROA at 181)**. Although this statement is undoubtedly accurate, it begs the larger question.[11] The Food and Drug Administration (FDA) has indicated that the FDA will not interfere with the practice of medicine to the extent of policing off-label use of drugs. The FDA has indicated that state malpractice laws are the appropriate mechanism for the regulation of off-label use of drugs.[12] The FDA has taken the position that state tort liability is the Aappropriate source of control@ for off-label uses of prescription drugs.[13] Although off-label use of drugs is generally accepted in the medical profession, the off-label use of EDTA to treat atherosclerosis and other vascular diseases most certainly is not. Commissioner Reine=s reliance on the general acceptance of the practice of off-label use itself

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[11]*See, generally*, Kaspar J. Stoffelmayr, Comment, *Product Liability and AOff-Label@ Uses of Prescription Drugs*, 63 U. Chicago L. Rev. 275 (Winter 1996).

[12]*See, e.g., Ramon v. Farr*, 770 P. 2d 131 (Utah 1989).

[13]48 Fed. Reg. 26, 733; Kaspar J. Stoffelmayr, Comment, *Product Liability and AOff-Label@ Uses of Prescription Drugs*, 63 U. Chicago L. Rev. 275, n. 36 (Winter 1996)(citing 48 Fed Reg at 26,733).

does not support his specific findings in favor of respondent. An off-label use of an FDA approved drug must still be non-negligent under applicable state tort law. Non-negligence **B** or compliance with the applicable standard of care **B** requires general acceptance by physicians.

4. The *Frye* Rule Remains the Law in Missouri.

Under the *Frye* general acceptance standard, evidence in support of chelation therapy should not have been admissible in evidence in defense of this case. Missouri law is well settled on the standard that must be met in order to admit evidence, including expert testimony, derived from a scientific theory, principle, or new scientific technique. This standard originated in *Frye*, *supra*, which held a scientific theory, principle or new technique is admissible if its proponents establish that **A** in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs. *Id.* at 1014. Missouri adopted this standard for expert testimony on scientific evidence in both criminal and civil cases. *State v. Stout*, 478 S.W.2d 368, 369 (Mo. 1972); *Alsbach v. Bader*, 700 S.W.2d 823, 828-29 (Mo. banc 1985). The Eastern District Court of Appeals has recently reaffirmed that *Frye* remains the law in Missouri. *M.C. v. Yeargin*, supra, at 618-19 (Transferred to the Missouri Supreme Court and then transferred back to the Court of Appeals at which time original opinion was reinstated).

Missouri, however, added its own perspective to the *Frye* standard in *State v. Biddle*, 599 S.W.2d 182, 185 (Mo. 1980); *see also Alsbach*, 700 S.W.2d at 828 (**A** Court

adopted its own version of the theory underlying *Frye*@). *Biddle* addressed the question of admitting evidence derived from a polygraph test. In determining this question, the court framed its analysis on whether the scientific technique-in-question had gained wide scientific approval of its Areliability.@ 599 S.W.2d at 190-191; restated in *Alsbach*, 700 S.W.2d at 829 (new scientific technique must show deduction made has a general or wide acceptance in the relevant community of its reliability). General acceptance may not be found A>[i]f there is a significant dispute between qualified experts as to the validity of scientific evidence.=@ *State v. Kunze*, 998 P.2d at 990. 5.

Respondent=s Expert Testimony.

Respondent introduced expert testimony regarding the efficacy and safety of EDTA chelation therapy for applications and treatments outside the uses approved by the Federal Food and Drug Administration. **(Tr. 117, lines 21-22)**. The record shows that these non-FDA approved applications and treatments are not generally accepted in the scientific discipline in which it belongs. Specifically, respondent introduced expert testimony from Dr. Frackleton, Dr. Chappell, Dr. Charles Rudolph and himself, as an expert practitioner, that EDTA chelation therapy was efficacious and safe in treating cardiovascular disease, particularly arteriosclerosis. However, respondent and his experts spoke in terms of meeting the Astandard of care@ and did not define what they meant by that term. Therefore, respondent=s expert testimony did not rise to the level of substantial evidence. Based on the holdings in *Bever*, supra, at *5, *7, and *Ladish*, supra, at 634-35, all of respondent=s expert testimony in support

of EDTA chelation therapy therefore failed to rise to the level of substantial evidence which could effectively counter petitioner=s expert testimony that

respondent repeatedly failed to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of his profession.

In order for the Commission to consider such testimony, respondent must, under the above-stated *Frye* rule, demonstrate: 1) EDTA chelation has been generally accepted for these applications and 2) this Ageneral acceptance@ has wide scientific approval in the relevant scientific community regarding the reliability of the studies and trials respondent relies upon to demonstrate EDTA chelation=s efficacy and safety for the non-FDA applications and treatment claimed. Respondent has failed to present sufficient evidence to satisfy either requirement.

6. <u>EDTA Chelation Is Not Generally Accepted Within The Relevant Scientific Community.</u>

Respondent is a general medical practitioner licensed specifically as an osteopathic physician. **(FOF #1,2, page 2)**. Under *Frye*, the relevant scientific community in this instance would be the medical community or, perhaps, the osteopathic medical community. The evidence in the record, however, does not show that this relevant scientific community has generally accepted EDTA chelation for the applications and treatments respondent claims. **(Pet. Ex. 24-28)**. Instead, the record contains substantial evidence that the osteopathic medical community in fact does not generally accept EDTA chelation as an efficacious and safe

application for the treatment of cardiovascular disease, particularly arteriosclerosis. **(*Id*.)**.

For instance, the American Osteopathic Association (AAOA@), an independent association of physicians organized to advance the philosophy and practice of osteopathic medicine, Adoes not endorse chelation therapy as useful for [any application or treatment] other than its currently approved and medically accepted uses.@ **(Petitioner=s Exhibit 24)**.

The position papers of the various organizations admitted into evidence demonstrate the state of the science on EDTA chelation therapy. These prestigious organizations have stated that it is the responsibility of the proponents of chelation to conduct appropriate studies demonstrating its effectiveness. The American Medical Association has said this about EDTA chelation therapy in 1994:

> There is no scientific documentation that the use of chelation is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer. If chelation is to be considered a useful medical treatment for anything other than heavy metal poisoning, hypercalcemia, or digitalis toxicity, it is the responsibility of its proponents to conduct properly controlled scientific studies to adhere to FDA guidelines for drug investigation and to disseminate study results in the usually accepted channels. The AMA believes that chelation for atherosclerosis is an experimental process without proof in efficacy.

(Petitioner=s Exhibit No. 26).

The American Heart Association's Task Force on New and Unestablished Therapies reviewed the available literature on the use of chelation and found "no scientific evidence to

demonstrate any benefit from this form of therapy." **(Petitioner=s Exhibit 25)**. The American College of Cardiologists has also issued a similar statement on EDTA chelation=s ineffectiveness. **(Petitioner=s Exhibit 27)**. There is also evidence in the record that the general medical community has not recognized EDTA chelation therapy for treating cardiovascular disease, particularly arteriosclerosis, as a generally accepted medical practice. **(Petitioner=s Exhibit 24-26; Dr. Meyers= Testimony, Tr. 115, lines 1-8, Tr. 188, line 24 to Tr. 189, line 6, Tr. 308-312; Petitioner=s Exhibit 13 (Deposition of Alfred Soffer, M.D.).**

7. <u>Petitioner=s Expert TestimonyBEDTA Chelation Therapy Not Generally Accepted By The Community of Physicians In The United States.</u>

Dr. David Meyers testified as to the Guldager study published in 1992 and the Van Rij study published in 1994 were large, well-designed studies, both of which concluded that EDTA chelation therapy was not effective in the treatment of atherosclerosis. **(Tr. 122-127)**. Dr. Meyers testified that the Guldager and Van Rij studies have both been generally accepted by medical science as scientifically valid. Dr. Meyers testified that as of the publication of the Van Rij study in 1994, EDTA chelation therapy in the treatment of atherosclerosis had been proven to be ineffective according to the requirements of medical science. The Van Rij study in 1994 replicated the results of the Guldager study in 1992 and authoritatively answered the question of the efficacy of EDTA chelation therapy in the treatment of atherosclerosis. **(Tr. 308-312)**.

8. <u>Respondent=s Expert Admits that EDTA Chelation Therapy Not Generally</u>

Accepted in Medical Profession or by Osteopaths in Particular.

Respondent=s primary expert witness, Dr. James P. Frackleton, M.D., squarely admitted that EDTA chelation therapy is not generally accepted in the medical profession in this country as efficacious for the treatment of atherosclerosis. **(Testimony of Dr. James P. Frackleton, Tr. 713, line 9, to Tr. 714, line 5)**. Dr. Frackleton, admitted in his testimony that EDTA chelation therapy is not generally accepted in either the allopathic community or the osteopathic community. **(*Id.*, Tr. 714, lines 15-19)**. Dr. Frackleton blamed the failure of organized medicine to embrace chelation therapy on Aignorance.@ **(*Id.*, at Tr. 713, line 23 to Tr. 714, line 19)**.

9. The Commission Uses a Negligence Standard to Decide an Evidence Question.

Commissioner Reine cites the case of *Ladish v. Gordon*, supra, for the proposition of law which he ultimately relies on to admit Respondent=s expert witness testimony. *Ladish v. Gordon* is a medical malpractice case which holds that a physician does not commit medical malpractice if the evidence indicates an Ahonest difference of opinion@ on appropriate treatment modalities. The *Ladish v. Gordon* opinion does not discuss, mention, or relate to the *Frye* evidentiary standard or the admission of expert medical testimony. The case involves the standard of care applicable when two or more alternative treatments are claimed to be appropriate medical care. The Ahonest difference of opinion@ standard is a negligence standard, not an evidentiary standard. Commissioner Reine used the wrong test and, not surprisingly, reached the wrong result.

Even here, Commissioner Reine ignores other applicable Missouri negligence case law. Missouri defines medical negligence as Athe failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of defendant=s profession.@ M.A.I. 11.06; *Gridley v. Johnson*, 476 S.W.2d 475 (Mo. 1972). The Missouri version of the Atwo schools of thought@ or Arespectable minority@ doctrine was expressed by the Missouri Supreme Court in *Haase v. Garfinkle* as follows: a Missouri physician is entitled to a wide range in the exercise of his judgment and discretion and cannot be found guilty of negligence, so long as there is room for an honest difference of opinion among competent physicians, unless it is shown that the course pursued was clearly against the course recognized as correct by the profession generally. *Haase v. Garfinkel*, 418 S.W.2d 108, 114 (Mo. 1967)(emphasis supplied).

Since it was established that the use of EDTA chelation therapy to treat atherosclerosis and other vascular diseases does not meet the generally accepted standard of care, Missouri substantive law applied to this evidentiary question would mandate that respondent=s expert testimony not be admitted, even if the Commissioner found Aan honest difference of opinion among competent physicians.@ After all, the Commissioner has no Aspecial expertise@ in medial matters and Amust make [his] decision based on the evidence before it, and in those cases where expert testimony is required, base it on competent evidence that satisfies the legal standard for defining negligence.@ *Bever*, 2001 WL 68307, *5.

10. The Relevant Scientific Community or AParticular Field to Which it Belongs@ Cannot Be Reasonably Held to Be Restricted to the Small Community of

Chelationists Who Are the Only Proponents of the Efficacy of Chelation.

The *Frye* standard holds that a scientific theory, principle or new technique is admissible if its proponents establish that Ain admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.@ (emphasis added). Obviously, the determination as to the Aparticular field to which it belongs@ can be a critical step in the decision as to whether to admit expert testimony under the *Frye* rule.[14] AEven tea leaf reading is generally accepted if the field surveyed is practicing tea-leaf readers.@[15] Without specifically saying so, Commissioner Reine in effect holds that the relevant Aparticular field@ in this case is Aphysicians who make their living practicing EDTA chelation therapy.@ In so finding, Commissioner Reine acted arbitrarily and unreasonably, and clearly acted against the logic of the circumstances, erred and abused his discretion.

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[14]*See, e.g., United States v. Williams*, 583 F.2d 1194, 1198 (2nd Cir. 1978), cert. denied, 439 U.S. 1117, 99 S.Ct. 1025, 59 L.Ed.2d 77 (1979)(the court notes that A[s]election of the >relevant scientific community,= appears to influence the result.@)

[15]Faigman, Kaye, Saks, and Sanders, *Modern Scientific Evidence*, *The Law and Science of Expert Testimony*, Vol. 1, Section 1-2.2, ftn. 17 (West 1997).

It has been recognized in the literature that A[t]he more narrowly a court defines the pertinent field, the more agreement it is likely to find.@[16] There is absolutely no existing Missouri case law which would support narrowing down the pertinent scientific field to only those who are known in advance to support the scientific proposition in question. Commissioner Reine=s arbitrary selection of chelation supporters as the pertinent field defeats the basic purpose of the *Frye* test, to base admissibility on the collective consensus and general considered judgment of the entire body of the pertinent field. Selecting only those who hold to a particular theory as the Aparticular field to which it belongs@ destroys the opportunity for the court to have the benefit of the consensus of experts.

In *Reed v. State*, 283 Md. 374, 391 A.2d 364, 377 (1978), the Maryland Court of Appeals stated as follows:

> AThe purpose of the *Frye* test is defeated by an approach which allows a court to ignore the informed opinions of a substantial segment of the scientific community which stands in opposition to the process in question.@

The Maryland Court of Appeals had the following comments on the subject of determining the

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[16]Faigman, Kaye, Saks, and Sanders, *Modern Scientific Evidence, The Law and Science of Expert Testimony*, ' 1-2.4, p. 9 (Admissibility of Scientific Evidence)(1997).

identity of the relevant scientific community:

> AThe identity of the relevant scientific community is, of course, a matter which depends upon the particular technique in question. In general, members of the relevant scientific community will include those whose scientific background and training are sufficient to allow them to comprehend and understand the process and form a judgment about it. In unusual circumstances, a few courts have held that the experts thus qualified might properly be from a somewhat narrower field.

391 A.2d at 368.

> AUnder the *Frye* test, however, this difficulty is largely avoided. As long as the scientific community remains significantly divided, results of controversial techniques will not be admitted, and all defendants will face the same burdens.@

391 A.2d at 371.

It is uncontroverted that the medical profession, as well as the Osteopathic branch of the medical profession, overwhelmingly rejects EDTA chelation therapy as effective in the treatment of vascular diseases. In fact, the medical profession is more than Asignificantly divided@ on the subject of the efficacy of EDTA chelation therapy. The medical profession is virtually unanimous in its rejection of EDTA chelation therapy and the record so demonstrates. Commissioner Reine=s reliance on Missouri=s negligence rules, holding that a Agood faith dispute@ about a particular treatment insulates a physician from malpractice liability, is not only inapposite, it is logically inconsistent with the basic theory underlying the *Frye* rule. At most,

Commissioner Reine=s finding of a Agood faith dispute@ shows that there is in fact a significant division in the medical profession as to the efficacy of chelation. In those circumstances, the *Frye* rule requires that expert testimony based on such a theory be excluded.

What Commissioner Reine essentially found is that those who believe in the efficacy of chelation therapy believe in the efficacy of chelation therapy. EDTA chelation therapy is simply not generally accepted in the fields of medicine and Osteopathic medicine, the particular fields to which it belongs in this specific case. **(Pet. Ex. 24; Tr. 1255 (Dr. Rudolph estimated that only 2% of the physicians practice chelation).** The expert testimony of Respondent=s experts should have been stricken from the record based on the *Frye* rule. Under the rule of *Ladish v. Gordon* such testimony did not constitute substantial evidence.

11. *Query:* If the substantive medical negligence law allows the standard of care to account for Aan honest disagreement among competent physicians,@ Atwo schools of thought@ or a Arespectable minority,@ how could a defendant physician ever make out his defense if the *Frye* rule would prevent him from offering expert testimony to prove that there are in fact Atwo schools of thought,@ a Arespectable minority@ or Aan honest disagreement among competent physicians?@

The law of a few states has developed what is known as the Atwo schools of thought doctrine,@ sometimes known as the Arespectable minority doctrine.@[17] The basic theory is that

[17]*See generally*, Glenn E. Bradford, *The ARespectable Minority@ Doctrine in*

a physician should not be found guilty of medical negligence if he adheres to a recognized treatment approach, even if the treatment approach is favored only by a minority in the profession. Although the theory is appealing, in practice the theory has been difficult to implement.[18] How is a judge or jury supposed to separate Arespectable@ physicians from those who are not? How many physicians does it take to make up a respectable minority? What does it take to qualify as a Aschool@ of thought? It has been argued widely that no court has come up with a workable definition of the Arespectable minority doctrine@ so that a judge or

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Missouri Medical Negligence Law, 56 J. Mo. Bar 326 (November-December 2000).

[18]See the discussion of the various state=s attempts to find a workable definition for Areasonable minority@ and Atwo schools of medical thought@ in the articles cited in footnote 9, above.

jury could implement the doctrine in an actual case.[19] As one commentator put it

[19]*See,* Comment, *Panacea or Pandora=s Box: The ATwo Schools of Medical Thought@ Doctrine after Jones v. Chidester*, 44 Wash. J. Urb. and Cont. Law 223 (1993). *See, also,* Newbold, *Medical Malpractice LawBPennsylvania=s ATwo Schools of Thought@ Doctrine Revisited: Definition and Application ClarifiedBUnderlying Goal ThwartedBJones v. Chidester*, 610 A.2d 964 (Pa. 1992). 66 Temp. L. Rev. 613 (1993).

after reviewing the case law, A[t]he test to determine whether a physician=s treatment falls under this >two schools of thought= doctrine is unclear.@[20] As seen in the above discussion, the Atwo schools of thought@ doctrine, while having an initial appeal from a policy standpoint, would ultimately seem to have contours too Afluid and imprecise@[21] to provide a workable test for an alternative standard of care in medical negligence and licensing discipline cases.

No reported Missouri case discusses the Atwo schools of thought doctrine@ or the Arespectable minority doctrine@as such. Missouri law defines medical negligence as Athe failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of defendant=s profession.@ M.A.I. 11.06; *Gridley v. Johnson*, supra. Section 334.100.2(5), RSMo 1994, defines medical negligence in effectively the same terms for licensing discipline cases.

The Missouri version of the Atwo schools of thought@ or Arespectable minority@ doctrine was expressed by the Missouri Supreme Court in *Haase v. Garfinkle* as follows: a Missouri

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[20]Comment, *Panacea or Pandora=s Box: The ATwo Schools of Medical Thought@ Doctrine after Jones v. Chidester*, 44 Wash. J. Urb. and Cont. Law 223 (1993).

[21]Michael H. Cohen, *Complementary and Alternative Medicine, Legal Boundaries and Regulatory Perspectives*, page 58, The Johns Hopkins University Press (1998).

physician is entitled to a wide range in the exercise of his judgment and discretion and cannot be found guilty of negligence, so long as there is room for an honest difference of opinion among competent physicians, unless it is shown that the course pursued was clearly against the course recognized as correct by the profession generally. 418 S.W.2d at 114 (emphasis supplied).

Under Missouri law, general acceptance of the treatment in question by the profession controls both the threshold evidentiary issue and the ultimate negligence issue. Both issues turn on the general acceptance in the profession of the treatment in question. Stated another way, evidence that EDTA chelation therapy is not generally accepted in the medical profession would disqualify substantive testimony in support of the therapy under the *Frye* rule. Conversely, if such testimony were to be admitted, it would not be legally sufficient to establish the substantive defense under *Haase v. Garfinkle* in any case. Both evidentiary and substantive issues turn on the same test: general acceptance in the profession.

Of course, it would make no sense if the substantive law were to permit a physician to defend himself based on the Ahonest disagreement among competent physicians@ doctrine, but yet prevent him from proving up his defense because the minority school of thought was, by definition, not generally accepted, and thus not qualified for admissibility under the *Frye* rule. Under the authority of *Frye* and *Haase v. Garfinkle*, general acceptance by the medical profession controls both evidentiary and procedural issues. The rule of *Haase v. Garfinkle* harmonizes both the procedural and the substantive law. The expert testimony tendered by Dr. McDonagh did not meet the standards of *Frye* and should not have been admitted.

C. CONCLUSION

As held in *M.C. v. Yeargin*, supra, a factfinder abuses its discretion if it admits an

expert=s testimony not based on scientific principles generally accepted in the relevant scientific community. 11 S.W.3d at 619. Additionally, all of respondent=s expert witnesses testified in terms of the Astandard of care,@ rather than in the language of the statute. Such testimony does not rise to the level of substantial evidence. *Ladish v. Gordon*, *supra*.

Respondent took on the burden of proving that there was an Ahonest difference of opinion among competent physicians,@ as related to chelation therapy. The Commissioner found as a fact that there was an Ahonest difference of opinion@ over chelation therapy.[22] Essentially, respondent conceded that the medical profession as a whole does not accept chelation therapy but argued that the fact that there are approximately 1000 chelators in this country sets up an Ahonest disagreement among competent physicians.@ The burden of proof on this issue was clearly on respondent. Absent respondent=s expert testimony, there was no competent and substantial proof of an Ahonest difference of opinion@ over chelation.

IV. REQUEST FOR RELIEF

Petitioner requests that the Court reverse and set aside the ***Findings of Fact and Conclusions of Law*** of the Administrative Hearing Commission and remand this case to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s decision herein and specifically excluding any reliance on respondent=s expert

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[22]AHC *Findings of Fact and Conclusions of Law*, Appendix, page A-37 to A-38. The Commissioner cites the case of *Ladish v. Gordon*, 879 S.W.2d 623 (Mo. App. W.D. 1994). Although the Commissioner provides this as the rationale for resolving the procedural question of the admissibility of Respondent=s expert testimony, it appears also that this rationale was a part of the substantive ruling finding that the use of chelation therapy did not violate the standard of care.

testimony and written exhibits as to the effectiveness of EDTA chelation therapy, as proffered in support of the alleged scientific basis of EDTA chelation therapy.

II. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN FINDING THAT EDTA CHELATION THERAPY MEETS THE STANDARD OF CARE FOR THE TREATMENT OF ATHEROSCLEROSIS AND OTHER VASCULAR DISEASES, BECAUSE, EDTA CHELATION THERAPY IS NOT GENERALLY ACCEPTED WITHIN THE MEDICAL PROFESSION AS EFFECTIVE IN THE TREATMENT OF ATHEROSCLEROSIS OR OTHER VASCULAR DISEASES, AND, IN ADDITION, WHILE THERE MAY OR MAY NOT BE A AGOOD FAITH DISPUTE AMONG COMPETENT PHYSICIANS@ AS TO THE EFFECTIVENESS OF EDTA CHELATION THERAPY FOR THIS USE, IN THAT THE USE OF EDTA CHELATION THERAPY TO TREAT ATHEROSCLEROSIS OR OTHER VASCULAR DISEASES IS NONETHELESS AAGAINST THE COURSE RECOGNIZED AS CORRECT BY THE MEDICAL PROFESSION GENERALLY,@ AND SUCH TREATMENT THEREFORE DOES NOT MEET THE STANDARD OF CARE UNDER MISSOURI LAW THEREFORE ON THIS ISSUE THE AHC ERRONEOUSLY ANNOUNCED AND APPLIED MISSOURI LAW.

A. OVERVIEW

Assuming for the sake of argument that Respondent=s expert medical testimony was admissible, Petitioner still made out its case of Arepeated negligence@ against respondent based on his long-time use of EDTA chelation therapy to treat atherosclerosis and other vascular diseases. It was uncontroverted that EDTA chelation therapy is not generally accepted by the medical profession as meeting the standard of care for the treatment of atherosclerosis and other vascular diseases. Therefore, Respondent was guilty of Arepeated negligence@ based on the record before the Administrative Hearing Commission.

A Missouri physician is entitled to a wide range in the exercise of his judgment and discretion and cannot be found guilty of negligence, so long as there is room for an honest difference of opinion among competent physicians. The clear exception to this principle is when that a physician=s conduct was clearly against the course of conduct recognized as correct by the profession generally. *Haase v. Garfinkel*, 418 S.W.2d 108, 114 (Mo. 1967). As demonstrated in Point I, above, the use of EDTA chelation therapy to treat atherosclerosis and other vascular diseases is not generally accepted in the medical profession. Therefore, using EDTA chelation therapy to treat atherosclerosis and other vascular diseases is clearly against the course recognized as correct by the profession generally.

B. ARGUMENT

The Administrative Hearing Commission found that the use of EDTA chelation therapy to treat atherosclerosis and other vascular diseases was not negligence. The Commission based its decision on its finding that the exists Aan honest difference of opinion among competent physicians.@ However, the Commission ignored the proviso in the *Haase v. Garfinkle* rule to

the effect that an Ahonest difference of opinion@ will not provide a defense to medical negligence if it is shown that the Acourse pursued was clearly against the course recognized as correct by the profession generally.@ The record in this case established that the medical profession overwhelmingly rejected EDTA chelation therapy as a treatment for atherosclerosis and other vascular diseases. The use of EDTA chelation therapy in this way is clearly against the course recognized as correct by the profession generally and there would appear to be no room for Aan honest difference of opinion.@

1. <u>Commissioner Reine=s Explanation For The AHC Ruling.</u>

Commissioner Reine concludes that AMcDonagh has provided us with evidence that chelation therapy treatments provide relief to some people and cause physical harm to no one.@ **(COL, page 42)**. This statement demonstrates Commissioner Reine=s basic misunderstanding of his duty as fact finder under the Missouri law. Under Missouri law, the issue is not whether Commissioner Reine can be convinced that chelation therapy provides Arelief to some people,@ but rather whether the medical profession has been convinced that chelation therapy is generally effective to treat vascular and other diseases. Commissioner Reine=s personal opinion on the matter is clearly irrelevant.

It is clear from a reading of Commissioner Reine=s opinion that he is viewing Board discipline as *punishment* for a licensee. The underlying premise of much of Commissioner Reine=s opinion seems to be his belief that it is not fair for the Board to Apunish@ Dr. McDonagh for pursuing chelation and other related

activities. Commissioner Reine writes as if he believes that it is a foregone conclusion that the Board will revoke Dr. McDonagh=s license if Commissioner Reine finds any basis for discipline at all. It is well established in Missouri law that Board discipline is not considered to be punishment but action taken in the best interest of Missouri citizens. Discipline primarily gives the Board *control* over a licensee and his medical activities. What Commissioner Reine is really holding is that he does not believe that Dr. McDonagh ought to be punished for pursuing chelation therapy. In order to so hold he had to ignore the larger part of the evidence of record.

A further example of the policy decision nature of the Commissions= ***Findings of Fact and Conclusions of Law*** is finding of fact number 17, which states that A[s]everal states have passed laws allowing a doctor to perform any procedure on any patient who consents to it as long as the patient gives informed consent.@[23] There is no issue made out by the pleadings to which

[23]The Board has several times considered the wisdom of promulgating a rule that the use of EDTA chelation therapy is Aof no medical or osteopathic value.@ The Board has recently promulgated an administrative rule under Section 334.100.2(f), providing that EDTA chelation therapy is of Ano medical or osteopathic value.@ The Board's rule provides that patients may receive chelation therapy if and only if they sign a Board-mandated form of informed consent which provides information about the scientific research on chelation and

this finding could possibly relate. This finding is an explanation for what is in effect a policy decision, pure and simple. **(ROA at 182)**.

2. <u>EDTA Is a Prescription Drug Approved by the FDA for the Removal of Heavy MetalsBchelation Therapy Is AOff-label Use@</u>.

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states that the Board believes that EDTA chelation therapy has been proven to be ineffective for the treatment of vascular disease. A three-day waiting period is also required before a patient can begin to receive treatment. *See,* 4 CSR 150-2.165. This rule was effective November 1, 2001.

Although the FDA does not police the use of FDA-approved drugs by physicians in their everyday practice, a physician might still have a liability for injuries resulting from the unapproved use of a drug under state negligence law principles. In prescription drug cases, there is no defense of federal preemption.[24] Therefore, state law controls. The FDA has taken the position that state tort liability is the Aappropriate source of control@ for off-label uses of prescriptions drugs.[25] The FDA has also suggested that the off-label use of certain drugs has caused thousands of adverse reactions, including deformation, disability and death.[26] However, the FDA has only attempted to

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[24]*See, e.g*, *Pollard v. Ashy*, 793 S.W.2d 394, 403 (Mo. App. E.D. 1990); *See, generally*, Patrick A. Malone, *The Role of FDA Approval in Drug Cases*, Trial p.28 (November 1998).

[25]48 Fed. Reg. 26, 733; Kaspar J. Stoffelmayr, Comment, *Product Liability and AOff-Label@ Uses of Prescription Drugs*, 63 U. Chicago L. Rev. 275, n. 36 (Winter 1996)(citing 48 Fed Reg at 26,733).

[26]JAMA, July 3, 1991, Vol. 266, No. 1, *FDA Scrutinizes AOff-Label@ Promotions*, Medical News and Perspectives, p. 11. *See, also*, Payne, *Consumers at Risk: Off-Label*

exert control over the drug manufacturer=s promotion of off-label use,[27] and has not sought to otherwise interfere in the physician=s practice of medicine. One commentator has stated that Atort suits for medical malpractice remain the only existing mechanism for regulating off-label use . . . .@[28]

3. EDTA Chelation Does Not Meet the Standard of Care in The Treatment of Atherosclerosis and other Vascular Diseases.

Section 334.100.2(5) provides conduct that might be harmful or dangerous to the health of a patient or the public or incompetency, gross negligence, or repeated negligence in performing such duties are grounds for discipline. ARepeated negligence@ is defined as Afailure on more than one occasion, to use that degree of skill and learning ordinarily used under the

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Use of Medical Drugs and Devices, Trial, August 1998, p. 26.

[27]*Id.*

[28]William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 Food & Drug L.J. 247, 260 (1993).

same or similar circumstances by a member(s) of the licensee=s profession.@

Count I of the Board=s Complaint was directed at Respondent=s use of EDTA chelation therapy generally and is not based on a specific patient complaint. **(ROA at 2-4)**. Respondent testified he began using chelation in the early 1960s and was still using it at the time of the hearing in November, 1997. **(Tr. 864-66; 1121, lines 16-21).** The only FDA approved use for the drug EDTA is for removing heavy metals from the blood. **(Pet. Ex. 13, page 20, lines 7 to 8 (Deposition of Dr. Alfred Soffer))**. EDTA chelation therapy is not generally accepted in the medical profession as effective in the treatment of atherosclerosis and other vascular diseases. **(Dr. Meyers= Testimony, Tr. 117, lines 21-22, Tr. 115, lines 1-8)**. Respondent as a general practice treats patients with EDTA chelation therapy for atherosclerosis (also known as arteriosclerosis) and other vascular diseases. Such treatment does not meet the applicable standard of care.

From a review of the record, it does not appear that any of Respondent=s expert witnesses defined their testimony on standard of care in terms of the actual language of the statute. Section 334.100.2(5), RSMo, defines Arepeated negligence@ as Athe failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee=s profession.@ Therefore, under the authority of the *Bever v. State Board of Registration for the Healing Arts*, 2001WL 68307 *5, *7 (Mo. App. W.D. 2001) (Opinion No. WD57880),[29] in which this Court held that the

[29]The Board in the *Bever* case moved for transfer to the Missouri Supreme Court,

term Astandard of care@ was insufficiently precise to constitute competent and substantial evidence of medical negligence, Respondent=s defensive testimony in support of EDTA chelation therapy failed to rise to the level of substantial evidence.

4. <u>Testimony of Dr. David G. Meyers, M.D., Board Certified Cardiologist.</u>

Dr. David G. Meyers, a Board-certified cardiologist who is also Board-certified in internal medicine and preventive medicine, served as Petitioner=s expert witness at trial. **(Dr. Meyers= Testimony, Tr. 70, line 3, to Tr. 73, line 15)**. Dr. Meyers has done substantial work toward his Master=s degree in public health and is an expert in the manner in which medical science studies disease and determines safe and effective cures. ***(Id.)***. Dr. Meyers, prior to being involved in the present case, set out to study EDTA chelation therapy and wrote a

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which was granted. The Board later dismissed its appeal to the Supreme Court with the consent of Dr. Bever, in light of the fact that the Legislature had amended the Open Meetings Law to provide that Board disciplinary hearings may be held in closed session, thus mooting the issue present on that transfer.

substantial scientific paper reviewing the subject. **(Tr. 74, line 6, to Tr. 76, line 5)**.

Dr. Meyers concluded in his paper that EDTA does appear to be safe when offered in doses of no more than 3 grams per infusion (as per the ACAM Protocol). Further, Dr. Meyers concluded that although the proposed mechanism of action for EDTA was scientifically plausible, there was no scientifically valid evidence published that EDTA chelation therapy was effective. As Dr. Meyers pointed out at trial, his paper was published prior to the publication of the Van Rij study, which found that EDTA chelation therapy was not effective in the treatment of atherosclerosis. **(Tr. 75-77; Tr.82, lined 3-20)**. Based on the findings of the Van Rij study in 1994, Dr. Meyers believes that it has now been conclusively established that EDTA chelation therapy is not effective in the treatment of atherosclerosis and other vascular diseases.

Dr. Meyers testified that at the times Respondent treated L.J. and B.C., EDTA chelation therapy did not meet the standard of care for the treatment of atherosclerosis and other vascular diseases. At the times Respondent treated L.J. and B.C., the effectiveness of EDTA chelation therapy had not been established in a controlled trial; therefore, treatment of atherosclerosis and other vascular diseases with EDTA chelation therapy did not meet the standard of care. As of 1994, with the publication of the Van Rij study, it has been conclusively established by the highest form of scientific proof that in fact EDTA chelation therapy is not effective for the treatment of atherosclerosis and other vascular diseases.

Prior to 1989, there had never been a controlled trial of EDTA chelation therapy to determine its effectiveness in the treatment of atherosclerosis and other vascular diseases. For

a number of years, various physicians had issued case reports of an anecdotal nature which suggested that EDTA chelation therapy was effective in the treatment of atherosclerosis.

In 1992, Guldager and others published the results of a controlled trial which met the requirements of scientific proof of the highest level, a randomized, double-blinded, placebo controlled, clinical trial. Guldager studied the effects of EDTA chelation therapy on 153 patients with intermittent claudication, or leg pain caused by vascular insufficiency. Guldager=s study, generally accepted by the scientific and medical community, concluded that EDTA chelation therapy was no more effective than placebo in treating intermittent claudication. **(Tr. 123-24)**.

In 1994, Van Rij and others published the results of another controlled trial which met the requirements of scientific proof at the highest level, a randomized, double-blinded, placebo controlled, clinical trial. Van Rij=s study, which was generally accepted by the scientific and medical community, concluded that EDTA chelation therapy was no more effective than placebo in treating intermittent claudication. **(*Id.* at Tr. 125-127; Pet. Ex. 13, page 13, lines 1-6 (Dr. Alfred Soffer Deposition))**. As of the publication date of the Van Rij in 1994, when added to the findings of the Guldager study published in 1992, it was conclusively established by valid scientific proof in the form of two generally accepted controlled clinical trials that EDTA chelation therapy is not effective in the treatment of atherosclerosis and other vascular diseases. **(Dr. Meyers= Testimony, Tr. 127, lines 9-16)**. Although the chelationists have criticized the Guldager study, and Dr. Meyers has reviewed the Guldager study to evaluate the criticisms made, Dr. Meyers believes that the Guldager study is a valid study and the study is generally accepted by the medical profession. **(*Id.* at Tr. 127, line 17, to Tr. 129, line 18)**.

Dr. Meyers was not aware of any criticisms in the literature of the Van Rij study. **(*Id.* at Tr. 135, lines 8 - 11)**.

5. <u>The Hierchy of Proof of Safety and Effectiveness in Medical Science</u>.

Dr. Meyers explained the hierarchy of proof of safety and effectiveness in medical science at considerable length. **(Tr. 88, line 8, to Tr. 115, line 8)**. As set out by Dr. Meyers, the hierarchy of proof is as follows:

<u>Most Persuasive</u>	***Randomized Clinical Trial***
	Longitudinal Cohort Study
	Case Control Study
	Case Series
<u>Least Persuasive</u>	***Case Report--Single Patient***

According to Dr. Meyers, each step up the hierarchy of proof constitutes an effort to eliminate the play of chance, confounding, and bias. **(Tr. 91, line 9, to Tr. 92, line 10)**. ABias@ is illustrated by the preconceptions of particular testers, who might prefer to see success or failure of a given procedure. **(*Id*.)**. Patients generally desire to get better, so that also could constitute a bias which would compromise the objectivity of a particular result. **(*Id*.)**. AConfounding@ is where some other attribute that is not being taken into account can influence the result of an experiment. **(Tr. 93, line 12, to Tr. 94, line 16)**. APlay of chance@ means here what it means in everyday life. For example, in an experiment, there is always the chance that a subject will get better just by the play of chance. **(*Id*. at Tr.94, line 17, to Tr. 14)**. The

study of biostatistics is the attempt to look at the play of chance in any experiment and attempt to define its impact on the outcome of the experiment. **(Tr. 95, lines 10 - 14)**.

The hierarchy of scientific proof is a convention accepted generally by the preponderance of clinicians and experts in the field, in the field of medicine, the preponderance of physicians, both allopathic and osteopathic, practicing medicine. **(Dr. Meyers Testimony, Tr. 115, lines 1 - 8)**. There is no reason that EDTA chelation therapy could not be studied in a randomized controlled trial. **(*Id*., at Tr. 108, lines 10-13)**. In order to determine whether a given drug or other form of treatment is efficacious, and therefore within the standard of care, medical science demands that the best possible study be performed to prove that a drug or other treatment works or does not. **(*Id*., at Tr. 111, line 1, to Tr. 112, line 4)**. This would mean that the evidence required for proof of efficacy is the most valid scientifically that is attainable. **(*Id*.)**. In the case of EDTA chelation therapy, this would require a controlled trial establishing the efficacy of the therapy to treat the disease under investigation.

6. <u>Dr. Frackleton, Respondent=s Expert Witness, Admits that the Medical Profession and Osteopathic Branch of the Medical Profession Do Not Generally Accept Chelation.</u>

Respondent=s expert witness, Dr. James P. Frackleton, admitted that physicians generally and osteopathic physicians in particular do not generally accept chelation therapy.

(Testimony of Dr. James P. Frackleton, Tr. 713, line 23, to Tr.714, line 19).

As demonstrated in Dr. Frackleton=s testimony, Respondent and his expert witnesses were really conceding that EDTA chelation therapy does indeed not meet the standard of care, but arguing vigorously that the medical profession is wrong and that EDTA chelation therapy should be generally accepted. It was Commissioner Reine=s job to determine the content of the generally accepted standard of careBnot to make his own personal determination of whether the medical profession is right or wrong about EDTA chelation therapy.

7. The Burden of Proof on Two Schools of Thought Issue.

As the Board has proven that Respondent=s use of EDTA chelation therapy for treatment of atherosclerosis and other vascular diseases does not meet the generally-accepted standard of care, Respondent would seem to have the burden to prove his contention that there exists an alternative standard of care generally accepted by a respected minority of physicians and, further, that he followed such standard of care in his treatment of his patients. *Remley v. Plummer*, 79 Pa. Super. 117 (1922); *Jones v. Chidester*, 610 A.2d 964, (Pa. 1992).

In the Arizona case of *Leech v. Bralliar*[30], the court found that there was an alternative approach to care supported by a minority of physicians but that the defendant had not demonstrated that he followed the teachings of the minority in his use of the treatment. The Arizona court also put the burden of proof on the physician to prove up an accepted alternative standard of care and that he followed that particular methodology Once the plaintiff proves up the generally accepted standard of care, the burden of going forward with the evidence is

[30]275 F. Supp. 897 (D. Ariz. 1967).

clearly on the defendant. The defendant should also bear the burden of proof or risk of non-persuasion on the issue of whether his conduct is insulated by an accepted, alternative standard of care.[31] The Atwo schools of medical thought@ doctrine is effectively an affirmative defense and logically should be so treated procedurally.

[31] *Jones*, 610 A.2d at 969; *Bonavitacola*, 619 A.2d 1363,1368; *Tesauro*, 650 A.2d at 1082.

After *Jones v. Chidester*, later Pennsylvania cases considered the burden of proof issue as related to what is required to prove up the existence of an alternative school of thought. In the case of *Bonavitacola v. Cluver*,[32] the court of appeals held that the defendant professional carries the burden of introducing sufficient evidence that a Aconsiderable number@ of professionals agree with his treatment approach. In *Tesauro v. Perrige*,[33] the court of appeals held that the burden was on the defendant to produce Aadequate factual support for his claim that there are a considerable number of professionals who agree with the treatment.@

8. <u>Anecdotal Evidence</u>.

[32]619 A.2d 1363 (Pa. Super 1993).

[33]650 A.2d 1079 (Pa. Super 1994).

Determination of whether evidence is substantial is a question of law reviewable by this court. *Hurlock v. Park Lane Medical Center, Inc.*, 709 S.W.2d 872, 883 (Mo. App. W. D. 1985) Anecdotal reports of patient improvement presented by an expert constitutes the lowest level of scientific proof of efficacy. *Muzzey v. Kerr-McGee Chemical Corp.*, 921 F. Supp. 511, 518 (N.D. Ill. 1996). AAn expert=s reliance on >anecdotal= evidence as opposed to >empirical= findings decreases the reliability of the evidence.@[34] In the case of EDTA chelation therapy, anecdotal case reports might well be considered of even less value than would anecdotal reports about other types of treatment. The reason is that the physicians who prescribe EDTA chelation therapy appear to be quite effective in selling their chelation patients on the benefits of diet and exercise. Indeed, it is believed that EDTA chelation therapy includes diet and exercise as an integral part of the therapy. **(Tr. 704)**. Anecdotal evidence sponsored by an expert witness has little value as substantial evidence. Anecdotal evidence sponsored by a lay witness would seem to have none at all.

[34]Kurtis B. Reeg and Cawood K. Bebout, *What=s It All About, Daubert?*, MoBarJ (Nov/Dec 1997).

For the purpose of providing substantial evidence to the FDA that a proposed new drug is effective, personal testimonials simply do not meet the exacting standards required by the Federal Food, Drug and Cosmetics Act and implementing regulations and are dismissed as irrelevant. *Edison Pharmaceutical Co. v. Food & Drug Administration*, 600 F.2d 831 (D.C. 1979). Such strict and demanding standards bar anecdotal evidence that doctors Abelieve@ in the efficacy of a drug. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 37 L. Ed. 2d 207, 93 S. Ct. 2469 (1973). The *Weinberger* Court stated that the Asubstantial evidence@ requirement of 21 U.S.C. Section 355(d) reflects Congress= conclusion that the clinical impressions of practicing physicians and poorly controlled experiments do not constitute an adequate basis establishing efficacy. *See, generally*, 25 Am.Jur.2d *DRUGS AND CONTROLLED SUBSTANCES*, Section 105 (--Showing of Asafety@ and Aeffectiveness@ required; what constitutes Asubstantial evidence@), page 280-81. AThe hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.@[35] *Weinberger*, 412 U.S. at 619. ASubjective evaluations by

[35]The Court cites: Hearings on S. 1552 before the Subcommittee on Antitrust and Monopoly of the Senate Committee of the Judiciary, 87th Cong., 1st Sess., pt. 1, pp. 195, 282, 411-412.

selected patients are even more suspect.@ *Id.*

Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered under the applicable federal regulation. *21 C.F.R. section 130.12(a)(5)(ii)(c); United States v. Vital Health Prods., Ltd.*, 786 F. Supp. 761 (E.D. Wis. 1992). Since the Act speaks of Ainvestigations,@ the FDA has required drug manufacturers to submit at least two Aadequate and well-controlled@ studies showing the effectiveness of the drug. *Warner-Lambert Co. v. Heckler*, 787 F.2d 147 (3rd Cir. 1986).[36] The Supreme Court in *Weinberger* stated that the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act and the regulations issued thereunder, expressed Awell-established principles of scientific investigation,@ in their reduction of the Asubstantial evidence@ standard to detailed guidelines. Uncontrolled studies alone are not considered sufficient to show effectiveness, but the FDA will consider them as corroborative support. 21 CFR ' 314.111(a)(ii)(c).

Dr. Louis Goodman, Professor of Pharmacology, University of Utah College of Medicine, and co-author of the medical textbook, A*The Pharmacological Basis of*

[36]21 USCA ' 355(d) was amended in 1997 to provide that if it is determined, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, such data and evidence may be considered to constitute substantial evidence.

Therapeutics,@ testified before the Committee of Congress considering the 1962 amendments and Ainsisted that there must be›basic, original, clinical evidence that a drug is a useful drug and that the claims made by the manufacturer are valid.=@ Dr. Goodman stated to the Committee that Athe individual practicing doctor cannot be the judge.@ *Pharmaceutical Manufacturers Ass=n v. Richardson*, 318 F. Supp. 301, 306 (D.C. Del. 1970).

Because chelation patients are typically encouraged to adopt a more healthful diet and to begin a regular program of exercise, as confirmed by Respondent=s expert witness Dr. Frackleton, it is difficult to establish a cause and effect relationship for chelation in the treatment of atherosclerosis or any other disease. **(Tr. 710-11)**. It is possible, and admitted, that diet or exercise or some combination of both could account for any positive results noted in the patient. **(Tr. 709)**. If addition, as mentioned a number of times in the evidence, each practitioner might individually include supplementation by may of vitamins and minerals and other chemicals either in the infusion process itself or as an addition to the EDTA infusion. **(*Id*.)**. It is therefore impossible to conclude that EDTA chelation, in and of itself, has any meaningful causative role in patient improvement. **(Tr. 710-11)**.

A lay patient is clearly not qualified to give an opinion as to the effectiveness of EDTA chelation therapy. Causation of this type must be established with expert testimony. In addition to a basic issue of the competence of a lay witness to attribute results to particular therapies, the two patients in the present case also had what scientists describe as

Aconfounding variables,@ which would make attribution of their continued good health to the chelation treatments scientifically unsupportable. In everyday language, there were too many other factors which could have been responsible to give all the credit to the chelation therapy. In particular, medical science has long since accepted the results of testing which demonstrated that exercise alone**B**and diet alone**B**can help alter the progression of atherosclerosis. **(Dr. Frackleton=s Testimony, Tr. 706)**. Therefore, there would be no way to attribute patient improvement to the chelation in and of itself.

On the issue of Aconfounding variables@ for clinical patients based on the general use of exercise, diet, and vitamin therapy, Dr. James P. Frackleton testified as follows:

AQ But on any given patient, on any given patient, there would be no

way to fairly say that it=s due to the chelation per se, would there?

A I would agree with that.@

(*Id.*). Dr. Frackleton=s testimony on this issue would seem to be wholly at odds with the Commission=s apparent conclusion that patient testimony alone can provide substantial evidence to

support the Commissioner=s finding that EDTA chelation therapy complies with the standard of care in the treatment of circulatory disease.

Commissioner Reine credits chelation with benefitting some patients, although acknowledging that diet and/or exercise might be responsible for any good results. **(FOF, page 42)**. Even Dr. Frackleton admitted that case reports on chelation are subject to the error of Aconfounding variables.@ **(Tr. 709)**. Dr. Charles Rudolph, the expert witness who provided the examples of patient improvement which Commissioner Reine ultimately relied on, acknowledged that the course of EDTA chelation therapy also includes diet, exercise, and vitamins and minerals and admitted that none of the work done in his office in the study of EDTA chelation was done studying purely the effect of chelation in and of itself. **(Tr. 1366)**. Commissioner Reine acknowledged that benefit to a clinical patient from EDTA chelation therapy cannot be fairly assessed due to the complicating factors of exercise, diet, vitamins, other medication, etc., but then turned around one-hundred-eighty degrees and held that such evidence was good enough for the Commission to negate and overcome the Board=s substantial expert testimony and evidence that EDTA chelation therapy had not been generally accepted in the medical profession as effective in the treatment of vascular disease.

9. <u>The Fallacy of *Post Hoc Ergo Propter Hoc.*</u>

Commissioner Reine has fallen victim to the fallacy of the *post hoc ergo propter hoc* method of proof, condemned for generations by medical science and the courts. In other words, merely because something occurred <u>after</u> a patient takes up a program of chelation

therapy does not necessarily mean that it occurred because of the chelation therapy. The Missouri Supreme Court in *Green v. Ralston Purina Co.*, 376 S.W.2d 119 (Mo. 1964), considered a case in which the plaintiff=s chickens died after being feed the defendant=s feed. The Supreme Court rejected the plaintiff=s argument that the increased number of sick chickens proved by way of circumstantial evidence that the feed was contaminated. The Court held that this proof of causation was based on the theory of *post hoc ergo propter hoc* and did not constitute substantial evidence of causation.

In order to add atherosclerosis and vascular disease to the indications for use on the label of the drug EDTA, the FDA would have to be presented with Asubstantial evidence@ in the form of controlled clinical trials accepted by experts in the field as proving the efficacy of EDTA to treat such indications. Physician=s opinions based on clinical use, anecdotal tales of patient improvement, and lesser forms of testing would not be accepted as a substitute for well controlled clinical trials. As noted by the courts, the FDA regulations merely restate the well-established principles of scientific investigation long accepted by medical science. The Commission accepted evidence of effectiveness of EDTA chelation therapy that clearly would not be considered by the FDA in approving a new drug, including an approved drug for a new use. Physician clinical experience, patient testimonials, and uncontrolled studies would not meet the standards of the FDA or of medical science generally. The evidence submitted by respondent in support of the effectiveness of EDTA chelation therapy did not meet the standard of substantial evidence.

10. Commissioner Reine Finds That ASomething@ Is Helping Patients.

Commissioner Reine ultimately retreated to a general statement that Asomething@ is helping these people get better. However, that Asomething@ might well be diet, exercise, vitamins, mineral supplements, or some combination thereof. Although Respondent=s experts conceded that the presence of confounding variables would make it impossible to assess the effects of EDTA chelation therapy in a clinical setting, the Commissioner nevertheless was swayed by this type of evidence. Commissioner Reine states that Asomething@ is helping these patients. Petitioner did not question the efficacy of Asomething.@

Petitioner has no quarrel with advising patients to eat a healthy diet or to begin a program of regular exercise. The Board contendsBand proved by competent expert evidenceBthat EDTA chelation therapy is not generally accepted as effective in treating circulatory disease. ASomething@ might be helping some of these patients but nobody, expert, layman, or AHC Commissioner, can say that EDTA chelation therapy plays a role in helping clinical patients.

However, proof of medical causation requires expert testimony. Lay witnesses are not generally permitted to give opinions, only to recite facts observed. *Mohr v. Mobley*, 938 S.W.2d 319 (Mo.App.W.D. 1997). Although the two patients report the lack of deterioration in their conditions after beginning EDTA chelation therapy, no competent expert testimony was offered that any perceived improvement or lack of further deterioration was the result of the EDTA chelation therapy itself. Absent interpretive expert testimony, the bare factual testimony of the patients does not amount to substantial evidence that EDTA chelation therapy is effective in the treatment of vascular disease. *Stephen v. Lindell Hosp*., 681 S.W.2d 503 (Mo.App. E.D.

1984); *Biggerstaff v. Nance*, 769 S.W.2d 470 (Mo. App. S.D. 1989).

11. Patients Geraldine Hamilton and Tom Gerrity.

Patients Geraldine Hamilton and patient Tom Gerrity each testified that they followed the diet and exercise recommendations made by Dr. McDonagh, which all the experts agreed made attributing any patient improvement to chelation therapy very difficult. Respondent=s expert witness, Dr. Frackleton, admitted that either the diet or the exercise Bor a combination of both--could be responsible for patient improvement in vascular function. **(Tr. 709-10)**. In addition, both patients continued to take their heart medication as originally prescribed by their cardiologists. It would be impossible for an expert, much less a layman, to attribute the fortunate continuation of the good health of Mrs. Hamilton and Mr. Gerrity to chelation therapy and Respondent=s experts so admitted. Given the difficultly in establishing a cause and effect relationship for chelation in the treatment of atherosclerosis or any other disease, it is impossible to conclude that EDTA chelation, in and of itself, has any meaningful role in patient improvement or maintenance of continued good health. **(Tr. 709-11)**.

Ordinarily, proof of causation must be made by way of expert testimony. *Landers v. Chrysler Corp*., 963 S.W.2d 275, 279 (Mo. App. E.D. 1997). Medical causation is an issue not within the common knowledge or experience of lay understanding. Medical causation, which is not within the common knowledge or experience of lay understanding, must be

established by scientific or medical evidence showing the cause and effect relationship between the complained of condition and the asserted cause. *McGrath v. Satellite Sprinkler Systems Inc.*, 877 S.W.2d 704, 708 (Mo.App. E.D.1994); *Bever*, supra, at *5. Proper opinion testimony as to causal connection is competent and can constitute substantial evidence. *Landers*, supra, 963 S.W.2d at 279. It is clear that the issue of the effectiveness, or lack thereof, of chelation therapy in the treatment of vascular disease, is not an issue within the competency of a lay witness. *Knipp v. Nordyne, Inc.*, 969 S.W.2d 236, 240 (Mo.App. W.D. 1998). The principles established in the personal injury cases apply in the present case. A patient with no medical or scientific training or background is not competent to testify as to the medical cause of a particular condition or state of health, even his own.

A lay patient=s affidavit submitted on causation has been held not to constitute substantial evidence sufficient to outweigh contrary expert testimony in the consideration of a motion for summary judgment. *Greene v. Thiet*, M.D., 846 S.W.2d 26 (Tx. App. 1993). The medical conclusions of a lay witness cannot controvert the opinion of an expert on medical issues. *Id.* A lay witness in not competent to testify on complicated medical issues related to causation. *Id.*

a) Patient Geraldine Hamilton.

Mrs. Hamilton testified that she continued to take Cardiziem and Diltiazem, as prescribed by her cardiologist, as well as an aspirin a day. **(Tr. 471-72)**. In addition she adopted Dr. McDonagh=s recommendations as to a better diet and started to exercise regularly by walking. She testified that at the time of the hearing she was still walking two-and-a-half

miles a day. **(Tr. 480)**. Mrs. Hamilton has walked two to two-and-a-half miles a day since 1986. **(Tr. 480-81)**.

At the time of the hearing, Mrs. Hamilton had not even been to see Dr. McDonagh for some two years, but was a patient of Dr. O=Keefe of the Cardiovascular Associates Lipid Clinic at KU Medical Center, who had put her back on Cardiziem and Niacin. **(Tr. 474)**. Given the fact that Mrs. Hamilton continued to see her original cardiologist, who continued to prescribe medication for her, and that she adopted a substantial program of regular exercise, as well as drastically altering her previous diet in favor of fruits and vegetables, her continued good health could not reasonably be attributed to EDTA chelation therapy. There are simply too many confounding variables to attribute any positive health benefits to chelation therapy..

b) Patient Tom Gerrity.

Patient Tom Gerrity=s video deposition was played at the AHC hearing. **(Tr. 858)**. Likewise, patient Tom Gerrity continued to take medication prescribed by his original cardiologist, Dr. Rosemond. **(Deposition of Tom Gerrity, Exhibit N, page 26)**. After having chest pain in 1991, Mr. Gerrity had an angioplasty. His cardiologist put him on Procardia and Isosorbide, later replaced by Imdur. **(*Id*., at 38)**. Mr. Gerrity continued to see his cardiologist and take the prescribed medication, even as he began to take EDTA chelation therapy. Mr. Gerrity has had a prescription for Procardia since 1991 and has taken it daily. **(*Id*., at 29-30)**. Mr. Gerrity=s understanding was that Procardia was prescribed to Arelieve blockage,@ and Aassist in the blood pressure relief.@ Further, Mr. Gerrity continued to take nitroglycerin, as needed, for pain. **(*Id*., at 27-28)**. Mr. Gerrity has taken Isosorbide and then

Imdur since 1991. **(Id., at 31).** Mr. Gerrity testified that as soon as he started taking Procardia and Isosorbide in 1991 that he started to feel better, even before beginning chelation therapy. After beginning chelation therapy, Mr. Gerrity continued to see his cardiologist. **(*Id.*, at 33, 35, 36)**.

Additionally, Mr. Gerrity testified that he began to exercise regularly and eat the recommended, improved diet. **(*Id.*, at 43)**. He now eats steak once a week instead of three times a week, as well as more fish. **(*Id.*, at 45)**. Since he had his angioplasty, Mr. Gerrity has Acut out the fat.@ **(*Id.*)**. Dr. McDonagh prescribed vitamins, which Mr. Gerrity took. Mr. Gerrity either walks or rides a stationary bike three or four times a week. **(*Id.*, at 42, 16)**.

As with Mrs. Hamilton, there are simply too many different factors present which could account for Mr. Gerrity=s continued good health. He had an angioplasty in 1991, which presumably would have helped his circulation. Since that time he has drastically changed his diet, continued a program of regular exercise, and taken heart medications prescribed by his cardiologist. Although Mr. Gerrity attributes his continued good health solely to EDTA chelation therapy, it is clear that an unbiased observer could not reasonably draw such a conclusion. There are too many other factors which could account for his continued good health. To attribute his continued good health solely to the results of EDTA chelation therapy would be total speculation.

C. CONCLUSION

Commissioner Reine ultimately concluded that "something" was "helping" some of Dr. McDonagh's patients. Dr. McDonagh made the argument that, even if his expert testimony was excluded under *Frye*, the patient testimony would support findings for Dr. McDonagh. In the absence of competent expert testimony, the patient testimony referred to cannot be considered as competent and substantial evidence supporting Dr. McDonagh's defense that EDTA chelation therapy is effective in the treatment of vascular diseases. Medical causation issues clearly require expert testimony. Even expert testimony based on the experience of Mrs. Hamilton and Mr. Gerrity would not constitute substantial evidence, as conceded by respondent's expert witnesses. If a qualified expert could not reasonably draw a conclusion on causation based on clinical patient experience, then certainly a lay witness could not himself.

Furthermore, in reviewing the record, it does not appear that any of Respondent's expert witnesses defined their testimony on standard of care in terms of the actual language of the statute. Section 334.100.2(5), RSMo, defines "repeated negligence" as "the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of . . . licensee's profession." Based on this Court's holding *Bever v. State Board of Registration for the Healing Arts*, supra, the term "standard of care" is insufficiently precise to constitute competent and substantial evidence of medical negligence. *Bever*, 2001WL 68307 *7. Therefore, Respondent's defensive testimony in support of EDTA chelation therapy failed to rise to the level of substantial evidence. The Commissioner had no competent, substantial evidence to support a finding that EDTA chelation is effective in treating vascular

disease. Determination of whether evidence is substantial is a question of law reviewable by this court. *Hurlock v. Park Lane Med. Center, Inc.*, 709 S.W.2d at 883. Commissioner Reine=s vague impression that Asomething@ is helping these patients is a far cry from competent, substantial evidence of record demonstrating that chelation therapy is generally accepted.

The use by Respondent of EDTA chelation therapy for the treatment of atherosclerosis and other vascular diseases did not meet the applicable standard of care and thereby constitutes the failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by members of Respondent=s profession. **(Dr. Meyers= Testimony, Tr. 117 to 118**; **Pet. Ex. 13, page 29 (Dr. Alfred Soffer Deposition); Pet. Ex. 15, page 49, lines 1-7 (Dr. Saul Green Deposition); Pet. Ex. 24-28)**. Given Respondent=s admitted and continued use of EDTA chelation therapy for these purposes, Respondent is guilty of Arepeated negligence.@

D. REQUEST FOR RELIEF

Petitioner requests that the Court reverse and set aside the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand this case to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s decision herein to the effect that petitioner proved by competent and substantial evidence that respondent is guilty of Arepeated negligence@ and is subject to discipline under Section 334.100.2(5), RSMo. 1994.

III. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN THAT THE COMMISSION FAILED TO MAKE REQUIRED FINDINGS OF FACT AND CONCLUSIONS OF LAW ON PETITIONER=S CLAIM IN ITS COMPLAINT TO THE EFFECT THAT RESPONDENT MISREPRESENTED THAT ATHEROSCLEROSIS, DIABETES, GANGRENE AND NUMEROUS OTHER DISEASES CAN BE CURED BY EDTA CHELATION THERAPY, BECAUSE THE LAW REQUIRES THE COMMISSION TO MAKE SPECIFIC FINDINGS OF FACT ON CONTESTED FACT ISSUES, IN THAT THE COMMISSION SHOULD HAVE FOUND THE FACTS IN FAVOR OF THE BOARD ON THE MISREPRESENTATION CLAIM, BASED ON THE SUBSTANTIAL EVIDENCE OF RECORD DEMONSTRATING RESPONDENT=S MANY STATEMENTS THAT CHELATION THERAPY CAN CURE NUMEROUS DISEASES.

A. OVERVIEW

A*Ask those who oppose chelation to cite either scientific evidence or studies on human beings that prove chelation does not work. There are none.*@

E.W. McDonagh, *Chelation Can Cure*

(Respondent=s Exhibit C-1, p. 26)

Even if EDTA chelation therapy met the applicable standard of care, which it does not, Dr. McDonagh still would not have been free to misrepresent and grossly exaggerate the scientific basis supporting the therapy. Section 334.100.2(4)(e), RSMo, provides that the Board may discipline a licensee who misrepresents that a disease can be cured Aby a method,

procedure, treatment, medicine, or device.@ This issue was totally ignored by the Administrative Hearing Commission. Petitioner does not believe Commissioner Reine made any findings or conclusions whatsoever on this issue. As the Court is well aware, Missouri law requires the Commission to make findings of fact on disputed issues. An administrative agency is required to set forth findings of fact on which its decisions are based to allow the court to test the sufficiency of the findings on review. *Missouri Bd. of Pharmacy v. Tadrus,* 926 S.W.2d 132 (Mo. App. W. D. 1996) (Section 536.090, RSMo 1994 requires findings of fact on disputed issues). An administrative agency cannot merely ignore issues raised and presented for decision. *Mineweld, Inc. v. Board of Boiler and Pressure Vessel Rules*, 868 S.W.2d 232 (Mo.App. W.D. 1994). When an administrative agency fails to make findings of fact responsive to issues presented for decision, there is nothing presented for judicial review. *Id.* An administrative agency must make findings of fact responsive to the issues framed to allow a reviewing court to perform the review allowed by law. *Id.* Here Petitioner asserted that Respondent made misrepresentations as to the ability of EDTA Chelation therapy to cure atherosclerosis and various other diseases, ailments, and infirmities. No findings were made by the Commission on this issue as raised in Petitioner=s Complaint.

B. ARGUMENT

1. Introduction.

Count I of the Complaint, paragraph 7, alleges that ARespondent has misrepresented that atherosclerosis and various other diseases, ailments, and infirmities can be cured by EDTA chelation therapy.@ **(ROA at 3)**. This allegation falls under Section 334.100.2(4)(e), RSMo.

No findings were made on this issue raised in petitioner=s Complaint. One need look no further than the title of Respondent=s book, *Chelation Can Cure*, which Dr. McDonagh offered into evidence, to conclude that he has in fact claimed that chelation can cure atherosclerosis and other degenerative diseases. **(Resp. Ex. C-1).**

As discussed above, there is no competent and reliable scientific evidence to support Respondent=s claims that EDTA chelation therapy can halt or reverse the progression of the process of atherosclerosis, that EDTA chelation therapy can halt or reverse degenerative diseases in general, or that EDTA chelation therapy can halt the process of human aging. The evidence in the record is to the contrary. Respondent misrepresented that EDTA chelation therapy can cure these diseases or conditions in that he has provided no competent and reliable scientific evidence to support such claims. **(Pet. Ex. 29, Resp. Ex. C-1)**.

Commissioner Reine abused his discretion by failing to make findings of fact and enter conclusions of law on the issue raised in Count I of the Board=s Complaint relating to allegations that respondent has misrepresented that EDTA chelation therapy can cure various diseases including atherosclerosis, diabetes, and other vascular diseases. As a result, this cause should be remanded back to the Commission for the entry of appropriate findings of fact and conclusions of law.

2. EDTA Chelation Therapy is Not Accepted By Medical Science As Effective.

Respondent=s use of EDTA chelation therapy for the treatment of atherosclerosis and other vascular diseases does not meet the applicable standard of care and thereby constitutes the failure to use that degree of skill and learning ordinarily used under the same or similar

circumstances by members of Respondent=s profession. **(Dr. Meyers= Testimony , Tr. 117-18; Petitioner=s Exhibit 13, page 29 (Dr. Alfred Soffer Deposition); Petitioner=s Exhibit 15, page 49, lines 1-7 (Dr. Saul Green Deposition); Pet. Ex. 24-28; Tr. 713-14, 1255).**

3. Respondent=s Claims that Chelation Can Cure Various Diseases.

Even if chelation as was effective to treat these diseases, Respondent would still not have the right to make false or unsupported claims about its effectiveness and the scientific evidence supporting the use of the treatment. The trial record reveals that Dr. McDonagh has been making outlandish and unsupported claims for chelation for years without regard for the actual state of the scientific record.

A good example of these overreaching claims for chelation is Petitioner=s Exhibit No. 29. Petitioner=s Exhibit No. 29 is a booklet provided over the years by Respondent to his patients and potential patients. **(Tr. 1174, lines 7-12)**. Petitioner=s Exhibit No. 29 is titled A*Reversing Degeneration and Aging Through Chelation*.@ The monograph was prepared for the lay public. **(Tr. 1176, lines 13-15)**. Respondent has given it out to patients or potential patients through the years and was still giving it out as of the time of the hearing in November, 1997. **(Tr. 1176, lines 16-21)**. The very title of this monograph illustrates the outlandish and unsupported claims made by Respondent for chelation over the years: A*Reversing Degeneration and Aging Through Chelation*.@

4. Respondent=s Misrepresentations in Booklet A*Reversing Degeneration and Aging Through Chelation*.@

Respondent=s booklet**,** A*Reversing Degeneration and Aging Through Chelation*,@ Petitioner=s Exhibit No. 29, includes a statement by Bruce Halstead, M.D., which provides

significant misinformation about EDTA chelation therapy. Dr. Halstead tries to make the case that EDTA chelation therapy has been proven safe and effective. Dr. Halstead wrote his paper in 1974 and it apparently was revised in 1982. As of 1982, as we have seen, no controlled trial had ever conclusively established EDTA chelation therapy as safe and effective in the treatment of atherosclerosis. That did not stop Dr. Halstead from claiming that:

> A review of the medical literature reveals that the practice of EDTA chelation therapy has been well established in the U.S. since the 1950s.
>
> * * *
>
> [t]he drug has received U.S. FDA acceptance in the past and the efficacy, mechanism of action, and safety factors are not new to the American medical community.

(Pet. Ex. 29, inside back front cover preceding page 1).[37] In reality, the FDA has only approved EDTA for the treatment of heavy metal poisoning. Dr. Halstead implies that the FDA has approved EDTA for atherosclerosis. He further implies that efficacy, mechanism of action and safety are accepted in Athe American medical community@ with the ambiguous statement that Athe efficacy, mechanism of action, and safety factors are not new to the American medical community.@ **(Id.)**. Not new, perhaps, due to the ongoing debate about EDTA chelation, a debate on which 99% of the AAmerican medical community@ then and now refuse to accept

[37] This material is also included in Respondent=s book, *Chelation Can Cure*; E.W. McDonagh, Platinum Pen Publishers, Inc., (1987), page 91-93. (Resp. Ex. C-1).

EDTA chelation therapy in the treatment of atherosclerosis.

Dr. Halstead also claims that:

> Clinical research on the medical applications of EDTA in atherosclerosis, and cardiovascular diseases, cardiac arrthymias and digitalis intoxication, heavy metal poisoning, sclerotic diseases, calcinosis and hypercalcemia, arthritis, hypertension and a variety of other diseases, has appeared in reputable medical journals in the U.S., France, Germany, Czecholslovakia, Russia, etc., since 1950. Extensive medical bibliographies have been compiled from time to time by the U.S. National Library of Medicine(1960-1975).

(*Id*.) This, of course, is as deceptive as can be. Halstead attempts to give the impression that a vast amount of medical literature supports the use of EDTA chelation therapy when we know that most of the literature actually published questioned the efficacy and safety of EDTA chelation therapy. Halstead does not even mention that the overwhelming consensus of organized medicine has refused to recognize EDTA chelation therapy as effective in the treatment of the listed diseases. He alludes to FDA approval but does not indicate that it has never been approved for the treatment of any of the diseases listed in the booklet.

In his summary to his booklet, A*Reversing Degeneration and Aging Through Chelation*,@ Respondent makes the following claims for EDTA chelation therapy.

SUMMARY

Chelation is a safe and unique treatment that will:

1. Reduce blood vessel calcium.
2. Clean out joint calcium.
3. Remove lead, which be measured in the urine.
4. Remove calcium which can be measured in the urine.
5. Restore normal function to the organs by improving blood flow to the cells that make up each organ. Balanced and proper nutrition is now available and can be utilized to reverse degeneration.

(McDonagh, Rudolph, 1982; Casdorph, 1981).

(Emphasis supplied). At the end of the monograph, the following claims are made by Respondent:

> Chelation is a sensible, deliberate detoxifying treatment that removes calcium, lead and other unwanted materials from the body. It takes time to do this. Along with the fluid infusions of EDTA goes a total program to detect and treat any other condition the patient might have. A re-balancing of the cellular chemistry and a proper diet aimed at continued health is provided the patient. Short daily exercise periods are recommended. This total approach will give the patient the ammunition he needs to fight and win the battle of degenerative disease that is becoming so prevalent in this country.
>
> We have observed that this treatment has enabled patients to get more fun out of life, and that=s what it=s all about, isn=t it? As things go - - degeneration goes on

> until the end result: self destruction. The Holistic health program including proper nutrition, proper vitamin and mineral supplementation, proper water, proper exercise and chelation can offer more time for active life, self preservation as it were. We feel it is foolish to run away from longer, sexier, vigorous life that the chelation concept can provide. You, yourself, can now stay in control of your fate. Allowing the arterial occluding phenomena to continue is unwise. We have a program to remove arterial scale and a program to keep blood vessels open in the future. You should feel much healthier and happier in the long run if you take the necessary minutes to consider the life style modifications mentioned above.

(Pet. Ex. 29, p. 20-21) (emphasis supplied).

It is interesting to note that Respondent=s clinic is giving out literature touting EDTA chelation as having a mechanism of action, i.e, removing calcium from arterial plaque, which has been abandoned by the chelation proponents for many years. **(Dr. Meyer=s Testimony, Tr. 83, line 2, to Tr. 85, line 3)**. As discussed at trial, the chelationists have essentially given up on the calcium removal theory in favor of the free radical theory of the mechanism of action of EDTA therapy. **(Tr. 85- 86, line 1).** Despite the fact that the calcium removal theory of the mechanism of action has been discredited even among chelators, Respondent=s clinic continues to put out literature claiming calcium removal as the proven mechanism of action. Perhaps this is so because the calcium removal theory is so easy to understand for lay persons, who might have more difficulty grasping the free radical theory.

Respondent flatly claims that he can stop the arterial occluding phenomena. Respondent claims in his above-referenced booklet A*Reversing Degeneration and Aging Through Chelation*,@ that Awe have a program to remove arterial scale and a program to keep blood vessels open in the future.@ As seen repeatedly throughout the trial, the medical-scientific literature presented by Respondent does not confirm this extraordinary claim. Indeed, the literature demonstrates that EDTA chelation therapy can do no such thing. There is no valid, accepted scientific proof that EDTA chelation therapy can reverse degenerative conditions, much less aging. There is no valid, generally accepted scientific proof that EDTA chelation therapy can Aremove arterial scale@ or Akeep blood vessels open in the future.@ Respondent=s booklet pamphlet, however, makes no mention whatsoever of the overwhelming scientific literature establishing that EDTA chelation therapy is ineffective in the treatment of atherosclerosis. Likewise, Respondent makes no mention of the fact that 99.9% of the medical profession dismisses chelation out of hand as unproven.

5. Respondent=s Representations that EDTA Chelation Therapy Can Cure Atherosclerosis and Other Vascular Diseases.

Respondent claims that there is no evidence of any misrepresentation to support a finding of misrepresentation and that Respondent has never claimed chelation can cure atherosclerosis. This is a surprising claim in light of the fact that Respondent=s book is titled A*Chelation Can Cure*.@ **(Respondent=s Exhibit C-1).** In fact, Respondent claims to one and all that chelation is effective in treating atherosclerosis. The book plainly states that Aa treatment process called EDTA chelation therapy has been available in this country for the past thirty years.@ Respondent flatly claims that A[i]t is more

effective than any other treatment.@ **(*Id.*, at 139)**. Furthermore, chapter 6 of *Chelation Can Cure* is entitled ACChelation Therapy and Atherosclerosis.@ **(*Id.*, at 42)**.

In literature promulgated by Respondent and his clinic, McDonagh Medical Center, Inc., Respondent has claimed that there is no scientific evidence or study on human beings which proves that chelation does not work. Respondent was well aware of the Guldager and Van Rij studies in 1992 and 1994, respectively, which found no benefit for atherosclerosis from chelation. Nevertheless, Respondent has continued to put out literature to the lay public in his book *Chelation Can Cure* making the claim that no study has ever been completed proving that chelation does not work. Rather than providing candid and complete information about the science supporting EDTA chelation therapy and allowing his patients to make an informed consent, Respondent has taken every possible opportunity to substantially overstate the case for chelation therapy. In the following pages, we detail Respondent=s misrepresentations and overstatements concerning chelation.

a) Respondent=s misrepresentations in his book, *Chelation Can Cure*.

In his book *Chelation Can Cure*, Respondent makes a number of claims that he can cure atherosclerosis with EDTA chelation therapy. An example:

> Must civilized man accept the prediction of more heart and artery disease? Are degenerative diseases the normal consequence of our society? I believe these diseases are unnecessary, and this kind of thinking unwise. Should we await the discovery of new miracle drugs, or a futuristic treatment approach to us, in the nick of time, from our predicament? The answer is *no*. A treatment

process called EDTA chelation therapy has been available in this country for the past thirty years. It is more effective than any other treatment. Results are a high quality, long lasting functional improvement.

Chelation neutralizes and removes the earliest and most basic cause of degenerative disease in the human body. Safe, thorough removal of the occluding materials that stick to the inside of the arteries is accomplished all over the body. Organs that have lost function because of circulatory embarrassment have their function restored, without the use of drugs.

(Respondent=s Exhibit C-1; page 139) (emphasis supplied). Respondent claims that EDTA chelation therapy Ais more effective than any other treatment.@ He says that A[s]afe, thorough removal of the occluding materials that stick to the inside of the arteries is accomplished all over the body.@[38] The Court should note that Respondent is making no qualification when he makes these blanket statements. What is Respondent=s scientific basis for claiming that EDTA

[38]Respondent=s own expert witness, Dr. Frackelton, contradicted this claim. Dr. Frackleton testified that chelation therapy can only maintain the status quo and prevent further plaque buildup but cannot Aremove@ plaque. Tr. 695.

chelation therapy Ais more effective than any other treatment,@ and that Aremoval of the occluding materials . . . is accomplished all over the body?@

It is significant in evaluating Respondent=s claim that the EDTA chelation therapy can remove the occluding materials that his own expert witness, Dr. James P. Frackleton, testified that EDTA chelation therapy did not remove existing arterial plaque but merely retarded or halted its further progression. **(Tr. 695, lines 18- 25).** Respondent is thus making claims for EDTA chelation therapy well beyond the claims made by other chelationists. Respondent is making specific claims that EDTA chelation therapy can Acure@ atherosclerosis and other diseases. Even the title of his book, *Chelation Can Cure,* demonstrates the unqualified nature of the claims made by Respondent for chelation. The book *Chelation Can Cure*, still being sold by Respondent=s clinic today, makes the following blatantly false introductory statement as to the state of scientific research:

AAsk those who oppose chelation to cite either scientific evidence or studies on human beings that prove chelation does not work. There are none.@

(Resp. Ex. C-1, page 26).

b) Respondent has made numerous claims about the effectiveness of chelation which are not literally true or which cannot be supported by the scientific literature.

Respondent, through his clinic=s patient literature and his personal published writings, has consistently made claims for EDTA chelation therapy that cannot be confirmed through established scientific inquiry. Respondent has represented, expressly and by implication, that

EDTA chelation therapy is an effective treatment for atherosclerosis. Respondent has represented, expressly and by implication, that he possessed and relied upon a reasonable scientific basis that substantiated the representation that EDTA chelation therapy is an effective treatment for atherosclerosis, at the times he made the representations. Respondent has repeatedly claimed that no scientific study exists which shows that chelation does not work. In truth and in fact, scientific studies do not prove that EDTA chelation therapy is an effective treatment for atherosclerosis. In truth and in fact, two major clinical trials have demonstrated no benefit from chelation for vascular disease.

6. Respondent=s Claims for Chelation Therapy Constitute Misrepresentation.

AMisrepresentation@ is a falsehood or untruth made communicating that a thing is in fact a particular way when it is not so, with the intent and purpose of deceit. MERRIAM -WEBSTER=S COLLEGIATE DICTIONARY 744 (10th ed. 1993); *Missouri Dental Bd. v. Bailey*, 731 S.W.2d 272, 274-75 (Mo. App. W.D. 1987). Under Missouri law, a misrepresentation must be made (1) knowing that the representation is false or made (2) without knowing whether it was true or false. *Emily v. Bayne*, 371 S.W. 2d 663 (Mo. App. 1963). Petitioner would suggest that the trial record demonstrates that Respondent made his claims that EDTA chelation therapy is effective to treat atherosclerosis and other vascular diseases without a substantial basis for believing that his claims were true. As such, Respondent=s claims for EDTA chelation therapy amount to misrepresentations under Missouri law. In particular, Respondent=s claims that the effectiveness of EDTA chelation therapy has been scientifically established is something that Respondent well knew not to be true. Respondent=s published claim that no scientific study has ever shown that chelation does not work is patently and demonstrably false.

7. ACAM and the Federal Trade Commission Enter Into Consent Agreement Over ACAM Claims for EDTA Chelation Therapy.

Respondent is a long-time member of the American College for Advancement in Medicine, known as ACAM. In Finding of Fact No. 15, the Commission made the following finding of fact in relation to Count I:

> A15. The American College for Advancement in Medicine (ACAM) is an organization of approximately 1,000 physicians worldwide. The ACAM=s position is that chelation therapy is a valid course of treatment for occlusive vascular disease and degenerative diseases associated with aging, such as diabetes and rheumatoid arthritis.@

The Federal Trade Commission recently took action on the marketing of EDTA chelation therapy by ACAM which would apply limitations to representations regarding chelation therapy in all states.[39] Although the FTC. consent agreement does not ban chelation

[39]The FTC Complaint against ACAM is posted on the world wide web at (http://www.ftc.gov/os/1998/9812/9623147cmp.htm). The FTC Notice, Agreement and Complaint appears at page 104 of the Record and following. The FTC material was entered into the trial record on the basis of Petitioner=s AMotion to Strike Matters Outside the

therapy in the several states, the consent agreement does materially limit the claims which ACAM, and implicitly individual practitioners, can make about chelation. The FTC=s action against ACAM and the resulting consent agreement was made a part of the record in the AHC. A review of the FTC=s actions on chelation therapy provides a good comparison for purposes of the present case. ACAM, as a group, was making much the same misrepresentations about chelation therapy as Dr. McDonagh, a stalwart member of ACAM, has been making on his own.

The Federal Trade Commission (FTC) and ACAM in late 1998 entered into a consent agreement under which ACAM agreed to cease and desist making unsubstantiated claims for EDTA chelation therapy such as (a) A(t)hat EDTA chelation therapy is an effective treatment for atherosclerosis,@ or (b) A[a]bout the effectiveness or comparative effectiveness of chelation therapy for treating or preventing any disease or condition related to the human circulatory system.@ The Agreement and Order was published for a period of public comment to close on March 31,1999.[40]

Record From Respondent=s Reply Brief, Or, In the Alternative, To Reopen the Record on the Issue of Whether Any State or the Federal Government Restricts the Clinical Use or Promotion of Chelation in the Treatment of Atherosclerosis.@ The Commission granted the Board=s motion to reopen the record and admitted the Board=s exhibits. (AHC Findings of Fact and Conclusions of Law, R. 62-134; R. 178).

[40]The FTC has posted the proposed Agreement and Order and related materials on the World Wide Web at http://www.ftc.gov/os/actions97.htm. The FTC Notice, Agreement and

Complaint appears at page 104 of the Record and following.:

The FTC has issued the following public statement about the consent agreement with ACAM over EDTA chelation therapy.

The Federal Trade Commission has accepted an agreement to a proposed consent order from the American College for Advancement in Medicine (›ACAM‹ or the ›proposed respondent‹). ACAM is an incorporated non-profit professional association comprised principally of physicians. The Commission has alleged that ACAM promotes EDTA chelation therapy to the public as an effective treatment for atherosclerosis, *i.e*., blocked arteries. Chelation therapy consists of the intravenous injection into the body of a chemical substance (ethylene diamine tetraacetic acid, (EDTA)), which, after bonding with metals and minerals in the bloodstream, is expelled through the body's excretory functions. ACAM promotes this service to consumers through print materials and a Web site.

* * *

The Commission has alleged that proposed respondent has made false and unsubstantiated claims in its advertising materials that are likely to mislead consumers concerning (1) the effectiveness of EDTA chelation therapy to treat atherosclerosis; and (2) the existence of scientific proof of the effectiveness of EDTA chelation therapy.

The proposed consent order addresses the alleged misrepresentations cited in the accompanying complaint by prohibiting proposed respondent from

representing in any future advertising for chelation therapy that EDTA chelation therapy is effective to treat atherosclerosis unless the representation is supported by competent and reliable scientific evidence (Part I.A).

In addition, the proposed order requires that proposed respondent have competent and reliable scientific evidence to support any claims about the effectiveness or comparative effectiveness of chelation therapy for any disease of the human circulatory system. (Part I.B).

* * *

The proposed consent order also requires that ACAM send a letter to its membership notifying them of the existence of the FTC order and advising them that any member who makes unsubstantiated advertising claims for chelation therapy could be subject to an enforcement order (Part IV).@ (Emphasis supplied)

(Federal Register/Vol. 63, No. 241/Wednesday, December 16, 1998/Notices (Federal Trade Commission [File No. 9623147] American College for Advancement in Medicine; Analysis to Aid Public Comment)). After a period of public comment, the FTC made its consent agreement with ACAM final as of July 13, 1999.[41] The Federal Trade Commission=s final

[41]*See*, FTC Announced Actions for July 13, 1999, *available at* http://www.ftc.gov/opa/1999/9907/bpamoco2-3.htm .

vote on approving the consent agreement after receiving public comment was 4-0.[42]

The essence of the FTC=s action against ACAM was the FTC=s charge that ACAM had no hard science to back up its extraordinary claims for the efficacy of EDTA chelation therapy in treating various diseases. The ultimate result was that ACAM did not even attempt to justify its outlandish claims about EDTA chelation therapy with scientific evidence. Respondent has made the same public claims for EDTA chelation therapy that ACAM has made. Since Respondent is one of the founding members of ACAM and has been a member of ACAM for many years, it could be argued that the now-prohibited representations about chelation on the ACAM web site are effectively his own representations. The respondent has no more scientific support for his wild claims about EDTA chelation therapy than ACAM did.

Like ACAM, Respondent has made broad claims for the effectiveness of EDTA chelation therapy not justified by the scientific record. Like ACAM, Respondent=s overblown claims constitute a serious misrepresentation which could work a disservice on Missouri citizens. The Board made its case in the AHC on misrepresentation. The Commissioner simply ducked the issue by not making any findings of fact or conclusions of law on this issue.

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[42]*See*, FTC Announced Actions for July 13, 1999, *available at* http://www.ftc.gov/opa/1999/9907/bpamoco2-3.htm .

10. The Administrative Hearing Commission Made No Findings on Misrepresentation Issues.

Determination of whether evidence is substantial is a question of law reviewable by this court. *Hurlock v. Park Lane Med. Center, Inc.*, supra, at 883. The AHC has the legal responsibility to make findings of fact and enter conclusions of law on contested issues. The only finding of fact even tangential to the misrepresentation issue is Finding of Fact No. 16, which finds that respondent has his patients sign a consent form Athat discusses the positive and negative aspects of chelation therapy and possible side effects.@ The Commission also made the finding that respondent Atells his patients that the therapy does not work on everyone.@ The Commission makes no other findings which appear to deal with the issues of misrepresentation raised by the Board in Count I.

Of course, once Respondent has misrepresented that chelation therapy can cure atherosclerosis, diabetes and other chronic diseases, having the patient sign an informed consent form negating everything previously said about the therapy cannot legally be considered as vitiating the original misrepresentations. More importantly, assuming for the sake of argument that an informed consent form vitiates prior misrepresentations, the informed consent form could only insulate Dr. McDonagh as to misrepresentations made to that particular patient. An informed consent form would only pertain to a particular patient and could not have the legal effect of vitiating the legal effect of prior misrepresentations made to the general public or even other potential patients. Respondent has made numerous

misrepresentations about chelation therapy in his published pamphlets and literature to the general public.

Section 536.130.2(3), RSMo. 1994, provides that the court must review the underlying administrative decision to determine if findings of fact are supported by competent and substantial evidence upon the whole record. For purposes of reviewing an administrative agency=s decision, Asubstantial evidence@ is evidence which has probative force and from which the trier of fact reasonably could find the issues in harmony therewith. *Halford v. Missouri State Highway Patrol*, 909 S.W.2d 362 (Mo.App. W.D. 1995).

An administrative agency is required to set forth findings of fact on which its decisions are based to allow the court to test the sufficiency of the findings on review. *Missouri Bd. of Pharmacy v. Tadrus*, 926 S.W.2d 132 (Mo.App. W. D. 1996)(Section 536.090, RSMo 1994 requires findings of fact on disputed issues). An administrative agency cannot merely ignore issues raised and presented for decision. *Mineweld, Inc.* , 868 S.W.2d at 234. When an administrative agency fails to make findings of fact responsive to issues presented for decision, there is nothing presented for judicial review. *Id.* An agency must make findings of fact on the issues framed to allow a reviewing court to perform the review allowed by law. *Id.*

C. CONCLUSION

Even if respondent=s consent form constituted a defense to previous misrepresentations about EDTA chelation therapy as to the individual patient signing the form, such a form would not relieve respondent=s responsibility for misrepresentations made to the

general public, the vast majority of whom will never see respondent=s disclaiming form. The Board seeks discipline for misrepresentations made generally, as well as to particular patients. The statute does not limit discipline for misrepresentations to those misrepresentations made directly to a patient. This allegation falls under Section 334.100.2(4)(e), RSMo, which provides a basis for discipline when a licensee has Amisrepresented that any disease, ailment or infirmity can be cured by a method, procedure, treatment, medicine, or device.@ Even an effective disclaiming informed consent form would not be effective as to nonBpatients.

D. REQUEST FOR RELIEF

Petitioner respectfully requests that this Court reverse and remand this case to the Administrative Hearing Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s Opinion and directions, and specifically finding that the substantial evidence of record mandates the finding that respondent has misrepresented that certain human diseases and maladies can be cured by EDTA chelation therapy within the meaning of Section 334.100.2(4)(e), RSMo.

IV. THE ADMINISTRATIVE HEARING COMMISSION ERRED IN ARBITRARILY REJECTING PETITIONER=S SUBSTANTIAL EVIDENCE THAT RESPONDENT FAILED TO KEEP AND MAINTAIN PATIENT RECORDS IN ACCORDANCE WITH

THE APPLICABLE STANDARD OF CARE, BECAUSE THE COMMISSIONER ARBITRARILY DECIDED THAT A PHYSICIAN CANNOT BE DISCIPLINED BASED ON INADEQUATE RECORD-KEEPING IN THE ABSENCE OF A STATUTE OR BOARD RULE MANDATING SPECIFIC RECORD-KEEPING DUTIES ON THE PART OF MISSOURI PHYSICIANS IN THAT THE STANDARD OF CARE ESTABLISHES RESPONDENT=S PATIENT RECORD-KEEPING RESPONSIBILITIES.

A. OVERVIEW

Perhaps the most glaring example of the arbitrary, capricious, and unreasonable nature of Commissioner Reine=s *Findings and Conclusions* are his findings and conclusions relative to Petitioner=s allegations of violations of the applicable standard of care in relation to Respondent=s patient record- keeping. Counsel for Dr. McDonagh has admitted that A[c]harting is an integral part of the [patient=s] care.@ **(ROA at 679)**. Commissioner Reine simply refused to accept Dr. Meyers= testimony as to the requirements of the standard of care as to medical records on the grounds that Ano Missouri law or regulation sets forth standards or recommendations.@ **(FOF #7, page 2)**.

Petitioner=s evidence demonstrated that Respondent=s patient records failed to meet the standard of care for the patients reviewed in that they do not contain a complete history and a physical examination prior to initiation of therapy, and they frequently do not even show a diagnosis. **(Dr. Meyer=s Testimony, Tr. 166, 178, 203**; **Petitioner=s Exhibit 11 (1989 ACAM Protocol)).** Commissioner Reine arbitrarily imposed his own personal requirement by insisting that a Missouri statute or administrative rule mandating the character and quality

of patient records must be in effect before a Missouri physician can be disciplined for substandard records.

Section 334.100.2(5), RSMo. 1994 (and all other relevant years) provides that a physician may be disciplined for Arepeated negligence.@ Negligence is defined as a breach of the standard of care. Petitioner=s uncontroverted expert testimony that Respondent repeatedly breached the applicable standard of care in his lack of care in keeping patient records constituted substantial evidence supporting discipline. Commissioner Reine basically just refused to accept Dr. Meyers= testimony as to the requirements of the standard of care as to medical records on the grounds that Ano Missouri law or regulation sets forth standards or recommendations.@ **(FOF #7, page2)**.

B. ARGUMENT

1. Dr. McDonagh=s Patient Records Do Not Meet the Standard of Care.

Dr. Meyers= testified that the standard of care required Respondent to document a complete history. **(Tr. 166)** Dr. Meyers testified that the standard of care required Respondent to document a complete physical examination or a physical appropriate to the complaints made. ***(Id.)*** Dr. Meyers testified that the standard of care required that Respondent document a diagnosis. ***(Id.)***. Dr. Meyers testified that in the case of the patient in question, Respondent failed to document a complete history, failed to document a complete physical examination or an examination appropriate to the complaints made, and further failed to document a diagnosis. ***(Id.)***. Respondent agreed in his testimony at trial that the physician should perform and record a Athorough head-to-toe, hands-on physical examination,@ as mandated by the ACAM Protocol. **(Tr. 1134).** Respondent also agreed that a physician should take and record a

complete medical history, as mandated by the ACAM Protocol. **(Tr. 1134).**

In Count IV, paragraph 40, of Petitioner=s Complaint, it is alleged by the Board that Dr. McDonagh failed to take and record a history and physical for patient B.C. Dr. Meyers testified as follows with regard to patient B. C.[43]:

AQ All right. Does the standard of care require that you document certain things?

A Yes.

Q. Does it require you document a complete history?

A. Yes.

Q. Was a complete history documented?

A. No.

Q. Does it require you document a complete physical examination or a physical examination appropriate to the complaints that are made?

A. Yes.

Q. Was there such an examination documented?

[43]Petitioner did not file a general Arecords count.@ Dr. Meyers testified that Dr. McDonagh=s patient records were deficient for several patients in several respects.

A. No.

Q. Does the standard of care require that you document a differential diagnosis?

A. No.

Q. Does it require that you document a diagnosis?

A. Yes.

Q. Is a diagnosis documented?

A. No.

Q. Nevertheless, were treatments for something or other begun?

A. Yes.

(Tr. 166-67).

Additionally, although Respondent himself introduced the ACAM Protocol for EDTA chelation therapy as an alternative standard of care, and although the ACAM Protocol provides clear requirements for record keeping, Commissioner Reine refused to find any violation of the standard of care. **(Tr. 207)**. The ACAM Protocol provides that a complete medical history should be obtained. **(Pet. Ex. 11).** The ACAM Protocol provides that Aa thorough head-to-toe, hands-on physical examination should be performed and recorded.@ (*Id*.)(emphasis supplied). The Commissioner makes a number of findings related to the ACAM Protocol and paraphrased the above quote from the Protocol as to record-keeping. However, the Commissioner omitted the requirement of the Protocol that the results of the exam be recorded. **(FOF # 41 to 51, page 14-17)**. ABefore beginning chelation therapy, the Protocol instructs

the doctor to take a complete medical history and perform a >thorough head-to-toe, hands-on, physical examination.@ **(FOF #45; Pet. Ex. 11, page 9).** Respondent repeatedly failed to record and maintain the records required by the ACAM Protocol. The record-keeping requirements of the ACAM Protocol were essentially the same as the general standard of care requirements testified to by Dr. Meyers.

Commissioner Reine basically just refused to accept Dr. Meyers= testimony as to the requirements of the standard of care as to medical records on the grounds that Ano Missouri law or regulation sets forth standards or recommendations.@ **(FOF #7)**. This is ironic because Commissioner Reine recognized in this same case that the Board Acould not be expected to set forth a rule on every potential act that might violate the standard of care that a doctor owes to a patient.@ **(COL, page 32)**. Why does the Commissioner require a written standard in the case of patient records but not in the case of other violations of the standard of care? The Commissioner is arbitrarily imposing an additional standard over and above what the Legislature has required in Section 334.100.2(5), RSMo.

2. <u>Commissioner Reine Wants it in ABlack and White.@</u>

Although Petitioner introduced effectively uncontroverted evidence that Respondent routinely and repeatedly failed to follow the applicable standard of care for record-keeping, which Respondent essentially admitted, Commissioner Reine just decided to engraft his own personal requirement onto the standard of care.

> ACommissioner Reine: What are you going to base your case on that they didn=t keep the right records? What are you going to give me to show he didn=t keep the right records? That some doctor says he didn=t keep the right records?@

***

> Ms. Levine: Well, and may I respectfully state, that whether the ACAM protocol says it or not, they=re trying to discipline him based on Missouri law or rule.
>
> Commissioner Reine: That=s exactly right. I want to know what standard you intend to do that on and I want to see it in black and white. Okay?@

(Tr. 1102-03)(Emphasis supplied). Neither Respondent nor the Commission has cited any Missouri case law to support the proposition that the proof supporting a violation of the standard of care on record-keeping is any different from the standard of care in any other facet of practice.

3. The Medical Profession Defines the Standard of Care, Not Commissioner Reine.

As the Court well knows, the terms Astandard of care,@ Astandard of practice@ and Agood practice@are informal, shorthand references to professional standards under negligence law, as defined in Missouri law. ARepeated negligence@ is specifically defined in Section 334.100.2(5), RSMo 1994. A>Repeated negligence= means the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of the applicant=s or licensee=s profession.@ The Healing Arts Practice Act therefore does not limit Arepeated negligence@ to violations of a Ablack and white@ law or rule. The Act hinges the standard of permissible physician conduct on the accepted *custom* of practitioners in the field. There is simply no requirement in the Healing Arts Practice Act or in Missouri case law limiting findings of Arepeated negligence@ to something done in

violation of a statute or administrative rule.

Petitioner presented evidence of the applicable custom in medicine by way of Dr. Meyers= testimony. There was no real evidence offered in contradiction to Dr. Meyers= testimony. In fact, Respondent more or less agreed that his records were deficient. His experts generally stated that they found no violations of the standard of care but failed to address the specific topic of the adequacy of the patient records. Testimony framed in terms of the Astandard of care@ does not constitute substantial evidence. *Bever v. State Board of Registration for the Healing Arts*, 2001WL 68307 *7 (Mo. App. W.D. 2001). Commissioner Reine has simply arbitrarily made the determination that he will personally require an additional element of proof over and above that mandated by the Healing Arts Practice Act.

4. Dr. McDonagh=s Attorney Gets it Right, Standard of Care Equates to Good Practice.

Ironically, when Commissioner Reine launched into his diatribe about the lack of a specific Board rule on record-keeping, it was counsel for Respondent who articulated the legal basis for the record-keeping requirement.

> ACommissioner Reine: While we=re on the record, Mr. Bradford, what statute or rule, CSR, requires people licensed by the Healing Arts Board to keep records?
>
> * * *
>
> Ms. Levine: No I don=t believe there is. I=ve researched it before. Now I know there is a standard of practice to be able to maintain notes.
>
> Commissioner Reine: Standard from where?

Ms. Levine: Good practice.@

(Tr. 1101). Counsel for Respondent gave Commissioner Reine the correct answer. The record-keeping requirement arises from a standard of practice, as pleaded by Petitioner and as testified to by Dr. Meyers.

5. Dr. McDonagh Doesn=t Even Claim to Keep Adequate Records, Says Never Taught in School.

Dr. McDonagh tacitly admitted at trial that his patient records do not meet the standard of care. Dr. McDonagh had the following colloquy with his counsel at trial:

AQ. I want to take you back to the early days of your practice, starting in 1962 I believe you testified; is that right?

A. Yes.

Q. First of all, when you were in medical school or osteopathic school in 1958 through ›61, did they teach you how to appropriately chart patient progress?

A. No.

Q. Was there any course at all that was offered to you in your medical training providing you charting direction?

A. No.

Q. At any time in your post-graduate training have there been courses that you have taken about how to chart?

A. No.

* * *

Q. Now, going back then from the time you got out of school until up to now, have you ever attended a program regarding how to adequately chart?

A. No.

(Tr. 946-48).

Respondent=s experts did not attempt to defend his record keeping, as such. His counsel argued in the Circuit Court that since Dr. McDonagh=s expert witnesses generally testified that they found nothing in the patient records in question which violated the standard of care, then they must necessarily have meant that the records met the standard of care also. **(ROA at 679)**. Dr. Terry Chappell=s testimony is cited for the proposition that there was expert testimony to the effect that Dr. McDonagh=s records met the standard of care. **(ROA at 679)**. Of course, as discussed above, testimony framed in terms of Astandard of care@ without defining that phrase in the words of the statute, is not considered to be substantial evidence. *Ladish v. Gordon*, 879 S.W.2d 623 (Mo. App. W.D. 1994).

Dr. Chappell was specifically asked if he had an opinion Aconcerning the appropriateness of the treatment and the testing by Dr. McDonagh?@ No specific question was posed by counsel as to the adequacy of Dr. McDonagh=s charts and Dr. Chappell gave no specific testimony about the sufficiency of Dr. McDonagh=s charts, even though he reviewed them. None of Dr. McDonagh=s trial experts actually spoke to the specific question of whether his patient records met the applicable standard of care.

6. <u>Standard of Review: The Substantial Evidence Test</u>.

The evidence in support of an administrative agency finding must be sufficient to support the conclusion of a reasonable person after considering all of the evidence in the record as a whole, not just

the evidence that is consistent with the agency=s finding. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). In the *Universal Camera* case, the United States Supreme Court held that A[t]he substantiality of evidence must take into account whatever in the record fairly detracts from its weight.@ *Id.* AThis is clearly the significance of the requirement . . . [in APA Sec. 706] that courts consider the whole record.@ Davis and Pierce, *Administrative Law Treatise*, Third Ed. 1994, Sec. 11.2, p. 176 (Judicial Review of Adjudications). Therefore, this Court must consider all evidence of testing presented in the Administrative Hearing Commission in order to determine whether the Commissioner=s findings are supported by competent and substantial evidence upon the whole record.

7. <u>The Commission Is Not Free to Arbitrarily Reject Competent Expert Medical Testimony</u>.

Dr. Meyers testified that Dr. McDonagh=s patient records did not meet the standard of care. Neither Dr. McDonagh nor any of his experts really said anything different. The Commissioner did not phrase his decision on patient records as a question of Dr. Meyers= testimonial credibility. The Commission is not free to arbitrarily reject competent expert medical testimony. In *Wright v. Sports Associated, Inc.*, 887 S.W.2d 596 (Mo. banc. 1994), the Missouri Supreme Court held that an administrative law judge was not entitled to reject the uncontroverted expert testimony of a physician on the subject of causation based solely on his own understanding and experience. Commissioner Reine was not entitled to reject Dr. Meyers= essentially uncontroverted testimony that Dr. McDonagh=s repeated and unnecessary use of the hemoglobin A1c test did not meet the applicable standard of care. **C. CONCLUSION**

Unfortunately, the Commission made no real findings on the subject of patient records. An administrative agency is required to set forth findings of fact on which its decisions are based to allow the court to test the sufficiency of the findings on review. *Missouri Bd. of Pharmacy v. Tadrus*, supra. An administrative agency cannot merely ignore issues raised and presented for decision. *Mineweld, Inc.* , 868 S.W.2d at 234.

D. REQUEST FOR RELIEF

Petitioner requests that the Court reverse and set aside the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand this case to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s decision herein. Substantial credible evidence was presented that the patient charts did not meet the applicable standard of care. Respondent presented no substantial evidence to the contrary. This case should be remanded to the Commission for the entry of findings of fact and conclusions of law consistent with the substantial evidence of record.

V. THE COMMISSION ERRED IN FAILING TO MAKE THE REQUIRED FINDINGS OF FACT ON AND ARBITRARILY REJECTING SUBSTANTIAL EVIDENCE SUPPORTING PETITIONER=S REQUESTED FINDINGS OF FACT ON PETITIONER=S CLAIM THAT RESPONDENT REPEATEDLY CONDUCTED AND

PERFORMED INAPPROPRIATE AND UNNECESSARY TESTING ON PATIENTS IN VIOLATION OF SECTION 334.100.2(4)(c), AND (5), RSMo, TO-WIT: HEMOGLOBIN A1C TESTING, BECAUSE THE COMMISSION DID NOT HAVE LEGAL AUTHORITY TO ARBITRARILY REJECT UNCONTROVERTED EXPERT TESTIMONY AND ACCEPT MERE CONCLUSORY, SKETCHY AND SLIGHT EXPERT TESTIMONY NOT CONSTITUTING SUBSTANTIAL EVIDENCE, IN THAT PETITIONER PRESENTED SUBSTANTIAL EVIDENCE DEMONSTRATING REPEATED INAPPROPRIATE AND UNNECESSARY TESTING ON PATIENTS BY RESPONDENT, WHICH EVIDENCE WAS UNCONTROVERTED IN THAT NO EXPERT WITNESS TESTIFIED THAT THE REPEATED HEMOGLOBIN A1C TESTING WAS ANECESSARY@ AND THERE WAS NO SUBSTANTIAL EXPERT TESTIMONY PRESENTED BY RESPONDENT THAT ANY OF THE QUESTIONED TESTING WAS ANECESSARY,@ THE AOBJECTIVE LEGAL STANDARD@ ESTABLISHED BY SECTION 334.100.2(4)(c), RSMO.

6. OVERVIEW

Petitioner alleged in its Complaint that Respondent performed a great deal of inappropriate and unnecessary testing on a number of his patients, in violation of the Missouri Healing Arts Practice Act, Section 334.100.2(4)(c), RSMo., and in violation of the applicable standards of care. This issue is presented in Counts VI through XIII.

Without providing any real rationale for his decision, Commissioner Reine concluded

that Respondent had not at any time violated the standard of care with regard to patient testing, apparently relying on Respondent=s general claim to be entitled to test broadly as a part of a preventive medicine approach. Commissioner Reine also cites the *pro forma* testimony of Dr. McDonagh=s testifying experts to the general effect that everything he did at any time was generally within the applicable standard of care.

In each of the testing-related counts, Commissioner Reine recited that AMcDonagh and his experts described the value and necessity of the testing.@ **(COL, page 66, Count XII)**. In one count, Commissioner Reine claimed that AFrackleton described the tests and gave the rationale behind ordering them.@ **(COL, page 57, Count VII)**(emphasis supplied). The Commissioner did not specifically find that any of respondent=s expert witnesses had testified that the testing was Anecessary,@ the Aobjective legal standard@ set out in Section 334.100.2(4)(c), RSMo.

7. ARGUMENT

It would be impossible to cover the particular evidence regarding all of the patient testing within the required limitations of an appellate brief. However, a good example of the testing in question was respondent=s employment of hemoglobin A1c testing.

Dr. David Meyers, Petitioner=s medical expert, testified that even in a preventive medicine context patient testing must be focused. **(Tr. 184-85).** In particular, the accepted standard of care[44] holds that

[44]Dr. Meyers, the Board=s primary expert witness, did define Astandard of care@ in terms of the statutory language of Section 334.100.2(5), RSMo. 1994. **(Tr. 174-76).**

a physician may not generally test for the presence of specific disease processes in the absence of some indication of some history, sign or symptom. However, a physician may legitimately test for things that might cause disease in the future, high cholesterol being a familiar example. The statute is consistent with Dr. Meyers= testimony, allowing discipline for repeatedly conducting testing which is not Anecessary.@

Petitioner made its case on Dr. McDonagh=s abuse of patient testing and neither Dr. McDonagh nor any of his expert witnesses presented any rationale as to why giving unnecessary tests was legitimate medical practice or, in fact, necessary. The Commission=s findings for Respondent on Counts VI through XIII of Petitioner=s Complaint were arbitrary, capricious, and inconsistent with the substantial evidence of record. The Commission does not have the authority to simply ignore substantial evidence. The Commissioner failed to make findings of fact on the hemoglobin A1c testing issue, as required by Missouri law.

1. Statutory Basis for Counts VI through XIII.

Section 334.100.2, RSMo Supp. 1990, 1991, 1992, 1993, 1994, provides as grounds for discipline:

> (4) Misconduct, fraud, misrepresentation, dishonesty, unethical conduct or unprofessional conduct in the performance of the functions or duties or any profession licensed or regulated by this chapter, including, but not limited to, the following:

(a) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation...

(c) Wilfully and continually performing inappropriate and unnecessary treatment, diagnostic tests or medical or surgical services;

(Emphasis supplied).

In addition, in each count it is charged that respondent is guilty of Arepeated negligence@ in overtesting the various patients, in violation of Section 334.100.2(5), RSMo. Counts VI through XII each represent an individual patient. Petitioner established by qualified expert testimony that Respondent=s patient testing violated the applicable standards of care and that Respondent in fact wilfully and continually performed inappropriate and unnecessary diagnostic tests, in specific violation of Section 334.100.2(4)(c).

2. The Board=s Expert Medical Testimony.

Dr. Meyers criticized Respondent for giving Geraldine Hamilton repeated hemoglobin A1c test (also called H-b-A-one-c)[45] as inappropriate and unnecessary. **(Tr. 220)**. The

[45]For general information on the hemoglobin A1c test, see A*The ABC=s of*

hemoglobin A1c test tests for one thing and one thing only: blood sugar levels for approximately the past few months. **(Tr. 220).**

Despite the fact that there was never an indication of a problem with blood sugar, Dr. McDonagh repeatedly performed a very specific test on Mrs. Hamilton without ever having the slightest indication of a glucose problem in the first place. Dr. Meyers testified that this test relates the average blood sugar over a period of time. **(Tr. 220).** Dr. Meyers testified that since there was no evidence of a history of diabetes or any test showing glucose intolerance in the first place, this test would be unnecessary and a violation of the applicable standard of care. **(Tr. 220).**

The hemoglobin A1c test is used to determine if high blood sugar readings are merely transient or whether they actually reflect a long-term condition of high blood sugar indicative of diabetes. Dr. Meyers testified as follows:

AQ. What is that (hemoglobin A1c) test?

Hemoglobin A1c Testing . . . The Best Test of Blood Sugar Control for People with Diabetes.@<http://www.va.gov/diabetes/docs/HbA1c.doc> (Provided by the Veteran=s Health Administration)

A. That is a test that measures the amount of sugar connected to the hemoglobin molecule and red blood cells.

Q. Why would you do such a test?

A. It is the best currently available record of the average amount of blood sugar or glucose in a person=s blood, as compared to testing the amount of sugar at the moment.

Q. Are you looking for diabetes?

2. Yes, sir.

Q. Was there any basis documented in this lady=s medical record for conducting that test?

A. No, sir.@

(Tr. 189).

* * *

Q. Hemoglobin A1c test, what is that test?

A. That is at test that relates the average blood sugar over a period of time.

Q. Do you have any criticisms of that test being given?

A. Yes.

Q. What=s your criticism?

A This lady has no indication of having diabetes or glucose intolerance, therefore, an unnecessary test.

Q Violation of the standard of care?

A Yes.@

(Tr. 220). There was no cross-examination of Dr. Meyers by Respondent=s counsel about Dr. Meyers= testimony that Respondent conducted inappropriate and unnecessary patient testing. (Tr. 314 through 414, 424 through 435).

3. Testing for the History of High Blood Sugar Where No Initial Indication of High Blood Sugar.

Respondent had Mrs. Hamilton=s blood sugar tested on a regular basis. There was no indication in her chart that she had a blood sugar problem in the first place. **(Tr. 220)**. Indeed, the general testing done on Mrs. Hamilton indicated that her glucose level was only between 91 and 104 at all times, well within the reference range of 65 to 115 mg/dl. (Petitioner=s Exhibit 5, page 36, 46). Despite the fact that there was never an indication of a problem with blood sugar, Dr. McDonagh performed a very specific test on Mrs. Hamilton over and over again without ever having the slightest indication of a glucose problem in the first place.

The standard of care requires that you do the basic screening test and determine if there are indications for more specific testing. Dr. McDonagh is putting the cart before the horse. Dr. Meyers testified that giving Mrs. Hamilton the hemoglobin A1c test in the absence of an indication of a blood sugar problem would constitute a violation of the applicable standard of care. **(Tr. 220)**.

A review of Geraldine Hamilton=s chart (Petitioner=s Exhibit 5) demonstrates that Mrs. Hamilton received the hemoglobin A1c test a number of times over a two-year period and that at no time was her score out of the reference range. For example, on February 2, 1987, a lab report from Mawd Laboratories showed that Mrs. Hamilton=s hemoglobin A1c testing (AGlyco-HGB@) was 5.7. **(Pet. Ex. 5, p. 35)**. On 2/23/87 it was 5.9. **(Id., at 36)**. On March, 20, 1987 it was 5.5. **(Id., at 37)**. On

October 6, 1987 it was 4.7. The reference range is shown as 3.5 to 6.0. **(Id., at 47)**. Mawd Laboratories provided this description of the testing on its report:

> AGlycohemoglobin analysis has been performed by high pressure liquid chromatography (HPLC). This technique allows us to report the hemoglobin A1c fraction in addition to the total A1 component. A decrease in the percentage of glycohemoglobin is suggestive of a positive response to blood glucose regulation in a diabetic patient.@

The hemoglobin A1c test is a sophisticated, expensive test for a very specific problem. There is no evidence in patient Geraldine Hamilton=s chart that she ever had the problem in the first place.

4. Hemoglobin A1c Testing on Other Patients.

With regard to patient Tom Gerrity, Respondent stated in the record that the patient did not have diabetes. **(Tr. 243).** He then performed the hemoglobin A1C test on Mr. Gerrity ten separate times over the next two years. Dr. Meyers testified that to do the hemoglobin A1c test ten times in a period of two years in a patient with no indication of a diabetes problem Ais amazingly poor care and truly excessive.@ **(Tr. 243)**. Dr. Meyers concluded that A[t]here is absolutely no indication for doing that test repetitively.@ **(Tr. 243)**. Dr. Meyers noted that the hemoglobin A1c test was repeated on Donald Starkenburg six times. **(Tr. 287-88).** Dr. Meyers testified that repeating this test on a patient with no indication of diabetes would violate the standard of care. **(Tr. 287-88).** Patient James Crimmings paid for the hemoglobin A1c

test some eight times without evidence of a diabetes or glucose intolerance problem, which would also violate the standard of care. **(Tr. 299-300)**.

5. Practice of Preventive Medicine Not a License to Perform Unnecessary Testing.

Commissioner Reine apparently accepted the argument that, since Respondent purports to practice preventive medicine, any possible test done on a patient automatically meets the standard of care. The Commissioner makes no specific finding on the question of Petitioner=s allegation that Respondent=s repeated use of the hemoglobin A1c testing was not shown to be Anecessary@ and fails to meet the applicable standard of care, other than to recite in general that Respondent=s experts said that all his many tests were fine and dandy. Dr. Meyers testimony as to the applicable standard of care squares with the requirements of the Healing Arts Practice Act that a licensee not conduct repeated, Ainappropriate@ or Aunnecessary@ testing.

AQ. Well, I suppose . . . as a part of a preventive approach, would it be reasonable to do a broader screening for more things than you might ordinarily do in a more traditional medical approach?

A. To do a broad screen to search for disease as yet undetected in general, no. To search for things that might cause disease in the future, for instance cholesterol, yes.

Q. Okay. Is it your testimony that these tests would fall into the first category?

A. Yes.@

(Tr. 190). With regard to patient Tom Gerrity, Dr. Meyers testified that to do the hemoglobin A1c test ten times in a period of two years in a patient with no indication of a diabetes problem Ais amazingly poor care and truly excessive.@ **(Tr. 243).**

6. Dr. McDonagh Makes a Profit Off Unnecessary Tests.

One might wonder why an insurance company for a patient would repeatedly pay for excessive and unnecessary testing. In contrast to some doctor=s offices, who merely bill outside lab costs directly through to the patient, Respondent=s clinic bills for an office visit for a blood test. **(Tr. 1360-61).** Therefore, the insurance company paperwork would show a patient visit charge instead of a charge for patient testing. Dr. Rudolph testified that the McDonagh Clinic makes a profit on every test it gives to a patient. **(Tr. 1360-61).** If a blood tests costs $90.00, the McDonagh Clinic charges $120.00 for an office visit. **(Tr. 1361)**. The record should reflect that Dr. McDonagh denied that this was the procedure followed in the clinic. **(Tr. 971-72).**

7. Respondent=s Expert Provides No Rationale for Repeated Hemoglobin A1c Tests.

Although Respondent argued, and the Commission apparently concluded, that holding oneself out as practicing Apreventive medicine@ provides unlimited leeway to utilize broader screening testing, Section 334.100.2(4)(c) clearly provides that a Missouri physician may be disciplined for Awilfully and continually performing inappropriate and unnecessary . . . diagnostic tests.@ The language of the statute clearly makes the assumption that not all possible tests are appropriate and that some patient testing can be Ainappropriate@ and Aunnecessary.@ Looked at another way, the Missouri State Legislature has decreed in the

Missouri Healing Arts Practice Act that patient testing must be Aappropriate@ and Anecessary.@ No expert witness testified that the repeated hemoglobin A1c testing was Anecessary.@ Absent such testimony, the Commissioner had no substantial evidence to justify ignoring Dr. Meyers= testimony that such repeated testing was unnecessary.

Despite Commissioner Reine=s broad claim that AFrackleton described the tests and gave the rationale behind ordering them,@ nowhere in the record does Respondent offer substantial evidence that the repeated hemoglobin A1c testing was Anecessary.@ Dr. Frackleton limited his testimony to the general, conclusory statement that Dr. McDonagh=s wholesale hemoglobin A1c testing Awas very appropriate@ Afor our type of practice.@ **(Tr. 666).** Dr. Frackleton did not offer a rationale as to why repeated testing would have been Anecessary.@ Dr. Frackleton did not make any claim at all that such repeated testing was Anecessary.@ It is difficult to see how the Commissioner could have decided that Dr. Frackleton=s *pro forma* defense of Dr. McDonagh=s hemoglobin A1c testing could have risen to the level of substantial evidence in the absence of specific testimony that the repeated hemoglobin A1c testing was Anecessary@ within the meaning of Section 334.100.2.(4)(c).

In his findings of fact for Count VIII of petitioner=s Complaint, related to patient Geraldine Hamilton, the Commissioner recited that Dr. Meyers testified that Aall of the tests except bone density were unnecessary, and thus McDonagh=s conduct in ordering them fell below the standard of care.@ **(Count VIIIBG.H., COL, page 59)**. Without specifically mentioning the hemoglobin A1c testing, the Commissioner makes the general finding that

AMcDonagh, Rudolph, Frackleton, and Chappell testified that the tests were necessary and appropriate.@ **(Id.)**.

A review of the trial transcript discloses that none of these witnesses actually testified that repeated hemoglobin A1c testing was Anecessary.@ **(Entire Record).** For example, Dr. Chappell=s testimony about patient G.H. does not discuss the necessity of repeated hemoglobin A1c testing. **(Tr. 843-44).** Dr. Chappell testified generally that the testing was Aappropriate.@ Dr. Chappell absolutely did not testify that the testing was Anecessary.@ This was typical of Dr. Chappell=s testimony about patient testing. Dr. Rudolph said nothing at all about patient testing in his testimony. Dr. Frackleton provided the *pro forma* testimony that hemoglobin A1c testing was Avery appropriate@ for Aour type of practice.@ Dr. Frackleton did not testify that the repeated hemoglobin A1c testing was Anecessary.@ Dr. McDonagh did not testify that the repeated hemoglobin A1c testing was Anecessary,@ other than to generally contend that he had never given a patient an unnecessary test, based on his Apreventive approach.@ **(Tr. 974).** Dr. McDonagh did not specifically testify why the repeated hemoglobin A1c test was Anecessary,@ or attempt to explain why continual, repeated hemoglobin A1c testing would be Anecessary.@ As noted, below, the 1984 ACAM Protocol for EDTA chelation therapy, applicable to patient Geraldine Hamilton=s testing done in 1987, does not provide for repeated hemoglobin A1c testing.

8. <u>The ACAM Protocol Is Not Supportive</u>.

The Commissioner leans heavily on the ACAM Protocol for EDTA chelation therapy. (*Findings of Fact and Conclusions of Law*, p. 14-17, Findings No. 41 through 51 (D. ACAM Protocol)(R. at 210). It appears that the 1984 ACAM Protocol would be the appropriate reference for patient Gertrude

Hamilton, who began seeing Dr. McDonagh in January, 1987. The Commissioner failed to note that the 1984 ACAM Protocol for EDTA chelation therapy provides for blood sugar testing only Awhen indicated by [the] patient=s history.@ **(Pet. Ex. 20)**. Among the 1984 ACAM Protocol=s recommended laboratory tests: AA two-hour post prandial blood sugar or glucose tolerance when indicated by patient=s history.@ **(Pet. Ex. 20, page 14 (Pre-treatment Evaluation; 4. Laboratory Tests)**(AThe laboratory tests listed below are to be performed on each patient prior to the beginning of chelation whenever possible.@).

The 1984 ACAM Protocol also provides that certain evaluations should be done during the course of chelation treatments. **(Pet. Ex. 20, page 17)**. The Protocol calls for lab testing of a routine urinalysis after every five treatments. The 1984 Protocol also calls for a creatinine clearance test after ten treatments. After specifying the required testing, the Protocol provides:

> 3. Patients with any other active medical problem should also have that problem monitored regularly (i.e., diabetics should be getting frequent blood sugar determinations, etc.). ***

However, the 1984 ACAM Protocol nowhere authorizes repeated, serial use of the hemoglobin A1c test in patients without diabetes or another glucose-related problem. The philosophy of the 1984 ACAM Protocol thus appears to be consistent with the testimony of Dr. Meyers, to the effect that testing should be keyed to the existence of signs, symptoms or another previous indication of the disease.

9. Standard of Review: The Substantial Evidence Test.

The Missouri Administrative Procedure Act, Section 536.130.2(3), RSMo. 1994, provides that the court must review the underlying administrative decision to determine if findings of fact are supported by

competent and substantial evidence upon the whole record. The evidence in support of an administrative agency finding must be sufficient to support the conclusion of a reasonable person after considering all of the evidence in the record as a whole, not just the evidence that is consistent with the agency=s finding. *Universal Camera Corp. v. NLRB*, supra, at 488. In the *Universal Camera* case, the United States Supreme Court held that A[t]he substantiality of evidence must take into account whatever in the record fairly detracts from its weight.@ *Id.* AThis is clearly the significance of the requirement . . . [in APA Sec. 706] that courts consider the whole record.@ Davis and Pierce, *Administrative Law Treatise*, Third Ed. 1994, ' 11.2, p. 176 (Judicial Review of Adjudications). Therefore, this Court must consider all evidence of testing presented in the Administrative Hearing Commission in order to determine whether the Commissioner=s findings are supported by competent and substantial evidence upon the whole record.

10. The Commission Is Not Free to Arbitrarily Reject Competent Expert Medical Testimony.

Dr. Meyers testified that Dr. McDonagh=s repeated use of hemoglobin A1c testing was inappropriate and unnecessary. **(Tr. 288)** Neither Dr. McDonagh nor any of his experts really said anything different. The Commissioner did not phrase his decision on testing as a question of Dr. Meyers= testimonial credibility. The Commission is not free to arbitrarily reject competent expert medical testimony. In *Wright v. Sports Associated, Inc.*, supra, the Missouri Supreme Court held that an administrative law judge was not entitled to reject the uncontroverted expert testimony of a physician on the subject of causation based solely on his own understanding and experience.

An administrative agency=s ability to disregard testimony is not unlimited, and in appropriate instances Missouri courts have found competent and substantial evidence lacking.

Barnes Hosp., 661 S.W.2d at 537 (A[I]n this instance the Commission has indulged itself too much latitude in choosing to disbelieve the evidence. * * * .@); *State ex rel. Kahler v. State Tax Comm=n*, 393 S.W.2d 460, 465 (Mo. 1965) (Commission cannot arbitrarily disregard testimony not impeached or shown to be disbelieved); *Biggs v. Missouri Comm=n on Human Rights*, 830 S.W.2d at 516-19; *Knapp v. Missouri Local Gov=t Employees Retirement Sys*., 738 S.W.2d 903, 913 (Mo. App. 1987) (physician=s reports in a disability benefits case; AAn administrative agency may not arbitrarily ignore relevant evidence not shown to be disbelieved.@).

Davis and Pierce in their *Administrative Law Treatise* set out a number of guidelines which courts have used in applying the test of substantive evidence. Several of those guidelines have application here:

> A(2) a finding contrary to uncontradicted testimony is not usually supported by substantial evidence;
>
> (3) evidence that is slight or sketchy in an absolute sense is not substantial evidence;
>
> (4) evidence that is slight in relation to much stronger contrary evidence is not substantial evidence;@

Davis and Pierce are here restating points made is by Professor Cooper in an extensive study on the judicial application of the substantial evidence test.[46]

[46]Cooper, *Administrative Law: The Substantial Evidence Rule*, 44 A.B.A.J. 945,

Although the Commissioner discusses a number of the tests criticized by Dr. Meyers, the Commissioner basically ignores the hemoglobin A1c testing issue, other than to make his blanket conclusion that all of the testing by Dr. McDonagh was acceptable.

2. CONCLUSION

Petitioner established by qualified expert testimony that Respondent=s patient testing violated the applicable standards of care and that Respondent wilfully and continually performed inappropriate and unnecessary diagnostic tests, in specific violation of Section 334.100.2(4)(c), RSMo. In addition, the repeated over-testing of patients constituted Arepeated negligence,@ in violation of Section 334.100.2(5), RSMo. Dr. Meyers= review of patient files demonstrated that Respondent had performed the hemoglobin A1c test up to ten times over two years on patients with no indication of high blood sugar in the first place. Dr. Meyers termed this a violation of the standard of care, Aamazingly poor care,@ and Atruly excessive.@

Dr. Meyers testified for Petitioner that such unnecessary testing was a violation of the standard of care. Although Dr. Frackleton offered some Aslight or sketchy general,@ testimony to the effect that giving the hemoglobin A1c test was Aappropriate@ for Aour kind of practice,@ no expert testimony was presented that such testing, and particularly repeated testing, was Anecessary,@ as required by the Healing Arts Practice Act. ASlight or sketchy@ testimony is often

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1002-1003 (1958).

not regarded as substantial evidence. Davis and Pierce, *Administrative Law Treatise*, Third Ed. 1994, '11.2 (Aspen Publishers, Inc.)

1. We Either Have to Be Specific about the AObjective Legal Standard@

Or We Don=t.

Although counsel for Respondent might argue that Petitioner is being hypertechnical in making such a big distinction between testimony that there was no expert testimony in the record that the repeated hemoglobin A1c testing was Anecessary,@ as opposed to testimony that it was Aappropriate,@ this Court has held that precise language in conformance with the statute is critical in medical disciplinary cases. For example, this Court previously held that the Board failed to prove negligence in a disciplinary case against a physician, where the Board=s expert physician failed to testify in the precise terms of the statute, the statute defining Arepeated negligence,@ as Athe failure on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member (sic) of the . . . licensee=s profession.@ Section 334.100.2.(5), RSMo. This Court held that the term Astandard of care@ was insufficiently precise to constitute competent and substantial evidence of medical negligence. *Bever v. State Board of Registration for the Healing Arts*, 2001WL 68307 *7 (Mo. App. W.D. 2001). Ironically, in the *Bever* case, counsel for respondent herein was the very person contending for the requirement of precision in terms. *Bever, supra.*

ANecessary@ is not equivalent to Aappropriate.@ Giving a pediatric patient a lollipop might well be appropriate, but it is certainly not necessary. Proving that something is Aappropriate,@ assuming for the sake of argument that such proof was present, would not equate to proof that

something is Anecessary.@ It would seem that if such precision of language is required in one such case, it should be required in all. In *Bever*, this Court said:

> AIf attorneys and expert witnesses are allowed to become sloppy in the use of terms such as 'accepted standards' and 'standards of care' without specifying at some point in the witness' testimony the meaning of those terms, experts will inevitably tend to rely upon their own views of acceptable practice rather than applying the objective legal standard.@ (quoting *Ladish v. Gordon* at 634-35).

The Aobjective legal standard@ in the present case is Anecessary.@ In addition, where the Legislature has used different terms such as Anecessary@ and Aappropriate,@ each such term must be presumed to have a different and distinct meaning of its own. ANevertheless, we do, in interpreting a statute, absent a statutory definition, give words their plain and ordinary meaning. *Am. Healthcare Mgmt., Inc. v. Dir. of Revenue,* 984 S.W.2d 496, 498 (Mo. banc 1999). Furthermore, we give effect, if possible, to every word and phrase. *Lora v. Dir. of Revenue*, 618 S.W.2d 630, 633 (Mo. 1981).@ Testimony that something is Aappropriate@does not equate to proof that something is Anecessary.@

In addition, Dr. McDonagh offered expert testimony to the effect that his testing Amet the standard of care.@ As discussed above, testimony framed in terms of the Astandard of care@ without defining that term in terms of the statutory language does not amount to substantial

evidence. *Bever v. State Board of Registration for the Healing Arts*, 2001WL 68307 *7 (Mo. App. W.D. 2001).

Petitioner=s proof that the repeated hemoglobin A1c testing was not Anecessary@ was therefore uncontroverted. The Commissioner found that the testing in question was testified to by Dr. Meyers as unnecessary. (AHC Findings of Fact and Conclusions of Law, Count VIIBG.H., p. 59). The Commissioner had no substantial evidence to support his implied finding that it was Anecessary.@ Absent such testimony, the Commission should have found a basis for discipline based on respondent=s violation of Section 334.100.2(4), RSMo, based on Dr. David G. Meyers= testimony that such testing was unnecessary.

As a further matter, it appears that there was no testimony presented to contravene the Board=s expert testimony that all of the questioned testing was unnecessary. There was no expert testimony presented that any such testing was necessary. Therefore, the Court should remand to the Commission for the entry of findings to the effect that all of the testing condemned by Dr. Meyers as unnecessary, which was not contravened by specific expert testimony that such testing was necessary, should be found to be unnecessary and violative of Section 334.100.2(4)(c), RSMo.

D. REQUEST FOR RELIEF

The Commissioner failed to make the required findings of fact and conclusions of law on the testing issues related to hemoglobin A1c and other testing and, to the extent made or implicit in the Comissioner=s decision, any such findings and conclusions were arbitrary, capricious, unreasonable and were unsupported by competent and substantial evidence upon the

whole record. Therefore, under the provisions of Section 536.140.2(3) and (6), RS Mo. 1994, respectively, the decision of the Commissioner should be reversed and remanded for the entry of new findings of fact consistent with the competent and substantial evidence of record. The Commission=s finding that the repeated hemoglobin A1c testing was Aappropriate@ and Anecessary@ is not based on substantial evidence.

In addition, the repeated overtesting of patients constituted Arepeated negligence,@ in violation of Section 334.100.2(5), RSMo. If testing is not Anecessary,@ then it is not standard of care treatment.

CONCLUSION

Petitioner respectfully requests that the Court reverse the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s Opinion herein.

1. Petitioner requests that the Court reverse and set aside the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand this case to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s decision herein and

specifically excluding any reliance on respondent=s expert testimony as proffered in support of the alleged scientific basis of EDTA chelation therapy and specifically excluding any reliance on respondent=s expert testimony and written exhibits as to the effectiveness of EDTA chelation therapy, as proffered in support of the alleged scientific basis of EDTA chelation therapy.

2. Petitioner requests that the Court reverse and set aside the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand this case to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s decision herein to the effect that petitioner proved by competent and substantial evidence that respondent is guilty of Arepeated negligence@ and is subject to discipline under Section 334.100.2(5), RSMo. 1994.

3. Petitioner respectfully requests that this Court reverse and set aside the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand this case to the Administrative Hearing Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s Opinion and directions, and specifically finding that the substantial evidence of record mandates the finding that respondent has misrepresented that certain human diseases and maladies can be cured by EDTA chelation therapy within the meaning of Section 334.100.2(4)(e), RSMo.

4. Petitioner requests that the Court reverse and set aside the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission and remand this case to the Commission for the entry of new findings of fact and conclusions of law consistent with the Court=s decision herein. Petitioner presented substantial credible evidence that Dr. McDonagh=s patient charts do not meet the applicable standard of care in multiple respects. Dr. McDonagh presented no substantial evidence to the contrary. This case should be remanded to the Commission for the entry of findings of fact and conclusions of law consistent with the substantial evidence of record.

5. The Commissioner failed to make the required findings of fact and conclusions of law on the testing issues related to hemoglobin A1c and other testing and, to the extent made or implicit in the Commissioner=s decision, were arbitrary, capricious, unreasonable and were unsupported by competent and substantial evidence upon the whole record. Petitioner presented substantial evidence that respondent=s patient testing, specifically the repeated hemoglobin A1c testing, was not Anecessary,@ as mandated by Section 334.100.2(4)(c), RSMo. Respondent presented no substantial evidence that such testing was Anecessary.@ Therefore, under the provisions of Section 536.140.2(3) and (6), RSMo 1994, respectively, the *Findings of Fact and Conclusions of Law* of the Administrative Hearing Commission of the Commissioner should be reversed and remanded for the entry of new findings of fact consistent with the competent and substantial evidence of record.

As a further matter, it appears that there was no expert testimony presented to contravene the Board=s expert testimony that all of the questioned testing was unnecessary, as set out in Counts VI through XIII of the Board=s Complaint. Therefore, the Court should remand to the Commission for the entry of findings to the effect that all of the testing condemned by Dr. Meyers as unnecessary, which was not contravened by specific expert testimony that such testing was necessary, should be found to be unnecessary and violative of Section 334.100.2(4)(c), RSMo. In addition, the repeated overtesting of patients constituted Arepeated negligence,@ in violation of Section 334.100.2(5), RSMo.

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CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing and virus-free computer disk was mailed, postage prepaid, this ___ day of February, 2002, to:

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_____

An Attorney For Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to Missouri Supreme Court Special Rule No. 1, Respondent hereby certifies that this brief complies with the limitations contained in Special Rule No. 1(b) and that, according to the word count feature in WordPerfect, the entire brief contains 30,695 words. Respondent further certifies that, pursuant to Special Rule No. 1(f), it is filing with this brief a computer disk which contains a copy of the above and foregoing brief, which was prepared using

WordPerfect 8.0, and Respondent also certifies that the disk has been scanned for viruses and is virus-free.

An Attorney For Petitioner